

## **OHRs Information Sheet Research Involving Medical Devices**

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**The following is a reproduction of the FDA Information Sheet on Medical Devices**

[U.S. Food and Drug Administration](#)

### **INFORMATION SHEETS**

#### **Guidance for Institutional Review Boards and Clinical Investigators 1998 Update**

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## **Medical Devices**

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A medical device is defined, in part, as any health care product that does not achieve its primary intended purposes by chemical action or by being metabolized. Medical devices include, among other things, surgical lasers, wheelchairs, sutures, pacemakers, vascular grafts, intraocular lenses, and orthopedic pins. Medical devices also include diagnostic aids such as reagents and test kits for *in vitro* diagnosis (IVD) of disease and other medical conditions such as pregnancy.

Clinical investigations of medical devices must comply with the Food and Drug Administration (FDA) informed consent and Institutional Review Board (IRB) regulations [21 CFR parts 50 and 56, respectively]. Federal requirements governing investigations involving medical devices were enacted as part of the Medical Device Amendments of 1976 and the Safe Medical Devices Act of 1990. These amendments to the Federal Food, Drug, and Cosmetic Act (the Act) define the regulatory framework for medical device development, testing, approval, and marketing.

Except for certain low risk devices, each manufacturer who wishes to introduce a new medical device to the market must submit a premarket notification to FDA. FDA reviews these notifications to determine if the new device is "substantially equivalent" to a device that was marketed prior to passage of the Amendments (i.e., a "pre-amendments device"). If the new device is deemed substantially equivalent to a pre-amendments device, it may be marketed immediately and is regulated in the same regulatory class as the pre-amendments device to which it is equivalent. (The premarket notification requirement for new devices and devices that are significant modifications of already marketed devices is set forth in section 510(k) of the Act. Devices determined by FDA to be "substantially equivalent" are often referred to as "510(k) devices". If the new device is deemed not to be substantially equivalent to a pre-amendments device, it must undergo clinical testing and premarket approval before it can be marketed unless it is reclassified into a lower regulatory class.

Investigational Device Exemption (IDE)

An investigational device is a medical device which is the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device. Clinical investigations undertaken to develop safety and effectiveness data for medical devices must be conducted according to the requirements of the IDE regulations [21 CFR part 812]. An IDE study may not necessarily commence 30 days after an IDE submission to FDA. Certain clinical investigations of devices (e.g., certain studies of lawfully marketed devices) may be exempt from the IDE regulations [21 CFR 812.2(c)]. Unless exempt from the IDE regulations, an investigational device must be categorized as either "significant risk" (SR) or "nonsignificant risk" (NSR). The determination that a device presents a nonsignificant or significant risk is initially made by the sponsor. The proposed study is then submitted either to FDA (for SR studies) or to an IRB (for NSR studies).

The IRB's SR/NSR determination has significant consequences for the study sponsor, FDA, and prospective research subjects. SR device studies must be conducted in accordance with the full IDE requirements [21 CFR part 812], and may not commence until 30 days following the sponsor's submission of an IDE application to FDA. Submission of the IDE application enables FDA to review information about the technical characteristics of the device, the results of any prior studies (laboratory, animal and human) involving the device, and the proposed study protocol and consent documents. Based upon the review of this information, FDA may impose restrictions on the study to ensure that risks to subjects are minimized and do not outweigh the anticipated benefits to the subjects and the importance of the knowledge to be gained. The study may not commence until FDA has approved the IDE application and the IRB has approved the study.

In contrast, NSR device studies do not require submission of an IDE application to FDA. Instead, the sponsor is required to conduct the study in accordance with the "abbreviated requirements" of the IDE regulations [21 CFR 812.2(b)]. Unless otherwise notified by FDA, an NSR study is considered to have an approved IDE if the sponsor fulfills the abbreviated requirements. The abbreviated requirements address, among other things, the requirements for IRB approval and informed consent, recordkeeping, labeling, promotion, and study monitoring. NSR studies may commence immediately following IRB approval.

IRB Review of the Protocol and Informed Consent

Once the final SR/NSR decision has been rendered by the IRB (or FDA), the IRB must consider whether or not the study should be approved. In considering whether a study should be approved, the IRB should use the same criteria it would use in considering approval of any research involving an FDA regulated product [21 CFR 56.111]. Some NSR studies may also qualify as "minimal risk" studies, and thus may be reviewed through an expedited review procedure [21 CFR 56.110]. FDA considers all SR studies to present more than minimal risk, and thus, full IRB review is necessary. In making its determination on approval, the IRB should consider the risks and benefits of the medical device compared to the risks and benefits of alternative devices or procedures.

*Also see these FDA Information Sheets:*

["Significant Risk and Nonsignificant Risk Medical Device Studies"](#)

["Sponsor-Investigator-IRB Interrelationship"](#)

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## Frequently Asked Questions About IRB Review of Medical Devices

### 1. What is meant by Class I, II and III devices?

The class distinction is made primarily on the level of risk to users/patients and, therefore, the level of FDA oversight needed to ensure that the device is safe and effective as labeled. Generally, but not always, this corresponds to logical risk evaluations.

Class	Controls	Products
Class I	General controls	crutches, band aids
Class II	Special controls	wheelchairs, tampons
Class III	PreMarket Approval	heart valves (known to present hazards requiring clinical demonstration of safety and effectiveness) - OR - not enough known about safety or effectiveness to assign to Class I or II

### 2. What is the difference between marketing approval under a 510(k) and under a PMA?

A 510(k) application demonstrates that a new device is substantially equivalent to another device that is legally on the market without a PMA. If FDA agrees that the new device is substantially equivalent, it can be marketed. Clinical data are not required in most 510(k) applications; however if clinical data are necessary to demonstrate substantial equivalence, the clinical studies need to be conducted in compliance with the requirements of the IDE regulations, IRB review and informed consent (21 CFR parts 812, 56 and 50, respectively).

### 3. Why should an IRB decide whether a device is non-significant risk (NSR)?

The sponsors (usually the manufacturer of the device) makes the initial decision whether a device imparts significant risk (SR) to study subjects or others. If so, the sponsor obtains an Investigational Device Exemption (IDE) from FDA. If the sponsor believes the device does not impart significant risk, IRB approval of a study as an NSR device can be sought. The NSR category was created to avoid delay and expense where the anticipated risk to human subjects did not justify the involvement of FDA. If the IRB agrees that the study is NSR, no submission to or review by FDA is necessary before starting studies in humans. If the IRB considers the study to be SR, the sponsor must obtain an IDE from FDA before proceeding with clinical studies.

### 4. What does FDA know about an NSR study?

"There is no requirement to report to FDA when an NSR study starts." The requirements for IRB review, informed consent, adverse event reporting and labeling still apply. In addition, the sponsor should understand that proceeding with an NSR study is at their risk (meaning that the FDA can later disagree) and they may voluntarily seek advice or inform FDA about the decision to proceed without filing an IDE with FDA.

### 5. How does an IRB decide whether a device is SR or NSR?

The IRB uses its best abilities, the information in the regulations and the guidelines, and the risk evaluation provided by the applicant. It can, as always, seek outside assistance. The IRB should have

written policies and procedures regarding device review. The information sheet "Significant Risk and Non-Significant Risk Medical Device Studies" provides additional guidance.

**6. Does an IRB that reviews medical device studies need written procedures for determining whether the device is SR or NSR?**

When the IRB determines that an investigation presented for approval as involving an NSR device actually involves an SR device, 21 CFR 812.66 requires the IRB to so notify the investigator and, where appropriate, the sponsor. 21 CFR 56.108(a)(1) requires the IRB to follow written procedures for conducting its initial review of research and for reporting its findings and actions to the investigator. The procedures followed in determining whether a study is SR or NSR should be included among those written procedures.

**7. Does FDA require IRB review of the off-label use of a marketed device?**

YES, if the off-label use is part of a research project involving human subjects. NO, if the off-label use is intended to be solely the practice of medicine, i.e., for a physician treating a patient and no research is being done.

**8. What is the meaning of exemption in 21 CFR 812.2(c)(2)?**

The exemption applies only to investigations in which 510(k)'d products are being used in accordance with the labeling cleared by FDA. Investigation of an off-label use of a 510(k) product takes it outside this exemption. A device subject to 510(k) remains "investigational" until the 510(k) is cleared by FDA and the investigational use is subject to the requirements of the IDE regulation, informed consent and IRB review (21 CFR 812, 50 and 56, respectively).

**9. Must an IRB review a clinical investigation being done after submission of a 510(k)?**

YES, if it's research the 21 CFR 50 and 56 regulations apply, and an IRB should review it. A 510(k) allows commercial distribution; it doesn't address research use. A 510(k) application can take time to process during which it remains an investigational product. It cannot be distributed except for investigational use until FDA clears the 510(k) application.

*Also see these FDA Information Sheets:*

["Medical Devices"](#)

["Significant Risk and Nonsignificant Risk Medical Device Studies"](#)

["Emergency Use of Unapproved Medical Devices."](#)

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**Significant Risk and Nonsignificant Risk Medical Device Studies**

The Investigational Device Exemption (IDE) regulations [21 CFR part 812] describe two types of device studies, "significant risk" (SR) and "nonsignificant risk" (NSR). An SR device study is defined [21 CFR 812.3(m)] as a study of a device that presents a potential for serious risk to the health, safety, or welfare of a subject and (1) is intended as an implant; or (2) is used in supporting or sustaining human life; or (3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject. An NSR device investigation is one that does not meet the definition for a significant risk study. NSR device studies, however, should not be confused with the concept of "minimal

risk," a term utilized in the Institutional Review Board (IRB) regulations [21 CFR part 56] to identify certain studies that may be approved through an "expedited review" procedure. For both SR and NSR device studies, IRB approval prior to conducting clinical trials and continuing review by the IRB are required. In addition, informed consent must be obtained for either type of study [21 CFR part 50].

#### Distinguishing Between SR and NSR Device Studies

The effect of the SR/NSR decision is very important to research sponsors and investigators. SR device studies are governed by the IDE regulations [21 CFR part 812]. NSR device studies have fewer regulatory controls than SR studies and are governed by the abbreviated requirements [21 CFR 812.2(b)]. The major differences are in the approval process and in the record keeping and reporting requirements. The SR/NSR decision is also important to FDA because the IRB serves, in a sense, as the Agency's surrogate with respect to review and approval of NSR studies. FDA is usually not apprised of the existence of approved NSR studies because sponsors and IRBs are not required to report NSR device study approvals to FDA. If an investigator or a sponsor proposes the initiation of a claimed NSR investigation to an IRB, and if the IRB agrees that the device study is NSR and approves the study, the investigation may begin at that institution immediately, without submission of an IDE application to FDA.

If an IRB believes that a device study is SR, the investigation may not begin until both the IRB and FDA approve the investigation. To help in the determination of the risk status of the device, IRBs should review information such as reports of prior investigations conducted with the device, the proposed investigational plan, a description of subject selection criteria, and monitoring procedures. The sponsor should provide the IRB with a risk assessment and the rationale used in making its risk determination [21 CFR 812.150(b)(10)].

#### SR/NSR Studies and the IRB The NSR/SR Decision

The assessment of whether or not a device study presents a NSR is initially made by the sponsor. If the sponsor considers that a study is NSR, the sponsor provides the reviewing IRB an explanation of its determination and any other information that may assist the IRB in evaluating the risk of the study. The sponsor should provide the IRB with a description of the device, reports of prior investigations with the device, the proposed investigational plan, a description of patient selection criteria and monitoring procedures, as well as any other information that the IRB deems necessary to make its decision. The sponsor should inform the IRB whether other IRBs have reviewed the proposed study and what determination was made. The sponsor must inform the IRB of the Agency's assessment of the device's risk if such an assessment has been made. The IRB may also consult with FDA for its opinion.

The IRB may agree or disagree with the sponsor's initial NSR assessment. If the IRB agrees with the sponsor's initial NSR assessment and approves the study, the study may begin without submission of an IDE application to FDA. If the IRB disagrees, the sponsor should notify FDA that an SR determination has been made. The study can be conducted as an SR investigation following FDA approval of an IDE application.

The risk determination should be based on the proposed use of a device in an investigation, and not on the device alone. In deciding if a study poses an SR, an IRB must consider the nature of the harm that may result from use of the device. Studies where the potential harm to subjects could be life-threatening, could result in permanent impairment of a body function or permanent damage to body structure, or could necessitate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to body structure should be considered SR. Also, if the subject must undergo a procedure as part of the investigational study, e.g., a surgical procedure, the IRB must consider the

potential harm that could be caused by the procedure in addition to the potential harm caused by the device. Two examples follow:

The study of a pacemaker that is a modification of a commercially--available pacemaker poses a SR because the use of any pacemaker presents a potential for serious harm to the subjects. This is true even though the modified pacemaker may pose less risk, or only slightly greater risk, in comparison to the commercially-available model. The amount of potential reduced or increased risk associated with the investigational pacemaker should only be considered (in relation to possible decreased or increased benefits) when assessing whether the study can be approved. The study of an extended wear contact lens is considered SR because wearing the lens continuously overnight while sleeping presents a potential for injuries not normally seen with daily wear lenses, which are considered NSR.

FDA has the ultimate decision in determining if a device study is SR or NSR. If the Agency does not agree with an IRB's decision that a device study presents an NSR, an IDE application must be submitted to FDA. On the other hand, if a sponsor files an IDE with FDA because it is presumed to be an SR study, but FDA classifies the device study as NSR, the Agency will return the IDE application to the sponsor and the study would be presented to IRBs as an NSR investigation.

#### IRB and Sponsor Responsibilities Following SR/NSR Determination

##### **If the IRB decides the study is Significant Risk:**

###### 1. IRB Responsibilities:

Notify sponsor and investigator of SR decision  
After IDE obtained by sponsor, proceed to review study applying requisite criteria [21 CFR 56.111]

###### 2. Sponsor Responsibilities:

Submit IDE to FDA or, if electing not to proceed with study, notify FDA (CDRH Program Operations Staff 301-594-1190) of the SR determination;  
Study may not begin until FDA approves IDE and IRB approves the study.  
Sponsor and investigator(s) must comply with IDE regulations [21 CFR part 812], as well as informed consent and IRB regulations [21 CFR parts 50 and 56].

##### **If the IRB decides the study is Nonsignificant Risk:**

###### 1. IRB proceeds to review study applying requisite criteria [21 CFR 56.111]

2. If the study is approved by the IRB, the sponsor and investigator must comply with "abbreviated IDE requirements" [21 CFR 812.2(b)], and informed consent and IRB regulations [21 CFR parts 50 and 56].

#### The Decision to Approve or Disapprove

Once the SR/NSR decision has been reached, the IRB should consider whether the study should be approved or not. The criteria for deciding if SR and NSR studies should be approved are the same as for any other FDA regulated study [21 CFR 56.111]. The IRB should assure that risks to subjects are minimized and are reasonable in relation to anticipated benefits and knowledge to be gained, subject selection is equitable, informed consent materials and procedures are adequate, and provisions for

monitoring the study and protecting the privacy of subjects are acceptable. To assure that the risks to the subject are reasonable in relation to the anticipated benefits, the risks and benefits of the investigation should be compared to the risks and benefits of alternative devices or procedures. This differs from the judgment about whether a study poses a SR or NSR which is based solely upon the seriousness of the harm that may result from the use of the device. Minutes of IRB meetings must document the rationale for SR/NSR and subsequent approval or disapproval decisions for the clinical investigation.

FDA considers studies of all significant risk devices to present more than minimal risk; thus, full IRB review for all studies involving significant risk devices is necessary. Generally, IRB review at a convened meeting is also required when reviewing NSR studies. Some NSR studies, however, may qualify as minimal risk [21 CFR 56.102(i)] and the IRB may choose to review those studies under its expedited review procedures [21 CFR 56.110].

#### Examples of NSR/SR Devices

The following examples are provided to assist sponsors and IRBs in making SR/NSR determinations. The list includes many commonly used medical devices. Inclusion of a device in the NSR category should not be viewed as a conclusive determination, because the proposed use of a device in a study is the ultimate determinant of the potential risk to subjects. It is unlikely that a device included in the SR category could be deemed NSR due to the inherent risks associated with most such devices.

#### **NONSIGNIFICANT RISK DEVICES**

Low Power Lasers for treatment of pain

Caries Removal Solution

Daily Wear Contact Lenses and Associated Lens Care Products not intended for use directly in the eye (e.g., cleaners; disinfecting, rinsing and storage solutions)

Contact Lens Solutions intended for use directly in the eye (e.g., lubricating/rewetting solutions) using active ingredients or preservation systems with a history of prior ophthalmic/contact lens use or generally recognized as safe for ophthalmic use

Conventional Gastroenterology and Urology Endoscopes and/or Accessories

Conventional General Hospital Catheters (long-term percutaneous, implanted, subcutaneous and intravascular)

Conventional Implantable Vascular Access Devices (Ports)

Conventional Laparoscopes, Culdoscopes, and Hysteroscopes

Dental Filling Materials, Cushions or Pads made from traditional materials and designs

Denture Repair Kits and Realigners

Digital Mammography [Note: an IDE is required when safety and effectiveness data are collected which will be submitted in support of a marketing application.]

Electroencephalography (e.g., new recording and analysis methods, enhanced diagnostic capabilities)

Externally Worn Monitors for Insulin Reactions

Functional Electrical Neuromuscular Stimulators

General Biliary Catheters General Urological Catheters (e.g., Foley and diagnostic catheters)

Jaundice Monitors for Infants

Magnetic Resonance Imaging (MRI) Devices within FDA specified parameters

Manual Image Guided Surgery

Menstrual Pads (Cotton or Rayon, only)

Menstrual Tampons (Cotton or Rayon, only)

Nonimplantable Electrical Incontinence Devices

Nonimplantable Male Reproductive Aids with no components that enter the vagina

Ob/Gyn Diagnostic Ultrasound within FDA approved parameters

Transcutaneous Electric Nerve Stimulation (TENS) Devices for treatment of pain  
Wound Dressings, excluding absorbable hemostatic devices and dressings (also excluding Interactive Wound and Burn Dressings)

## **SIGNIFICANT RISK DEVICES**

### **General Medical Use**

#### *Catheters:*

- Urology - urologic with anti-infective coatings
- General Hospital - except for conventional long-term percutaneous, implanted, subcutaneous and intravascular
- Neurological - cerebrovascular, occlusion balloon
- Cardiology - transluminal coronary angioplasty, intra-aortic balloon with control system
- Collagen Implant Material for use in ear, nose and throat, orthopedics, plastic surgery,
- urological and dental applications
- Surgical Lasers for use in various medical specialties
- Tissue Adhesives for use in neurosurgery, gastroenterology, ophthalmology, general and plastic surgery, and cardiology

### **Anesthesiology**

Breathing Gas Mixers

Bronchial Tubes

Electroanesthesia Apparatus

Epidural and Spinal Catheters

Epidural and Spinal Needles

Esophageal Obturators

Gas Machines for anesthesia or analgesia

High Frequency Jet Ventilators greater than 150 BPM

Rebreathing Devices

Respiratory Ventilators

Tracheal Tubes

### **Cardiovascular**

Aortic and Mitral Valvuloplasty Catheters

Arterial Embolization Devices Cardiac Assist Devices: artificial heart (permanent implant and short term use), cardiomyoplasty devices, intra-aortic balloon pumps, ventricular assist devices

Cardiac Bypass Devices: oxygenators, cardiopulmonary non-roller blood pumps, closed chest devices

Cardiac Pacemaker/Pulse Generators: antitachycardia, esophageal, external transcutaneous, implantable

Cardiopulmonary Resuscitation (CPR) Devices

Cardiovascular/Intravascular Filters

Coronary Artery Retroperfusion Systems

Coronary Occluders for ductus arteriosus, atrial and septal defects

Coronary and Peripheral Arthrectomy Devices

Extracorporeal Membrane Oxygenators (ECMO)

Implantable Cardioverters/Defibrillators

Laser Coronary and Peripheral Angioplasty Devices

Myoplasty Laser Catheters

Organ Storage/Transport Units

Pacing Leads

Percutaneous Conduction Tissue Ablation Electrodes

Peripheral, Coronary, Pulmonary, Renal, Vena Caval and Peripheral Stents  
Replacement Heart Valves  
RF Catheter Ablation and Mapping Systems  
Ultrasonic Angioplasty Catheters  
Vascular and Arterial Graft Prostheses  
Vascular Hemostasis Devices

**Dental**

Absorbable Materials to aid in the healing of periodontal defects and other maxillofacial applications  
Bone Morphogenic Proteins with and without bone, e.g., Hydroxyapatite (HA)  
Dental Lasers for hard tissue applications  
Endosseous Implants and associated bone filling and augmentation materials used in conjunction with the implants  
Subperiosteal Implants  
Temporomandibular Joint (TMJ) Prostheses

**Ear, Nose, and Throat**

Auditory Brainstem Implants  
Cochlear Implants  
Laryngeal Implants  
Total Ossicular Prosthesis Replacements

**Gastroenterology and Urology**

Anastomosis Devices  
Balloon Dilation Catheters for benign prostatic hyperplasia (BPH)  
Biliary Stents  
Components of Water Treatment Systems for Hemodialysis  
Dialysis Delivery Systems  
Electrical Stimulation Devices for sperm collection  
Embolization Devices for general urological use  
Extracorporeal Circulation Systems  
Extracorporeal Hyperthermia Systems  
Extracorporeal Photopheresis Systems  
Femoral, Jugular and Subclavian Catheters  
Hemodialyzers  
Hemofilters  
Implantable Electrical Urinary Incontinence Systems  
Implantable Penile Prostheses  
Injectable Bulking Agents for incontinence  
Lithotripters (e.g., electrohydraulic extracorporeal shock-wave, laser, powered mechanical, ultrasonic)  
Mechanical/Hydraulic Urinary Incontinence Devices  
Penetrating External Penile Rigidity Devices with components that enter the vagina  
Peritoneal Dialysis Devices  
Peritoneal Shunt  
Plasmapheresis Systems  
Prostatic Hyperthermia Devices  
Urethral Occlusion Devices  
Urethral Sphincter Prostheses  
Urological Stents (e.g., ureteral, prostatG)

**General and Plastic Surgery**

Absorbable Adhesion Barrier Devices  
Absorbable Hemostatic Agents

Artificial Skin and Interactive Wound and Burn Dressings  
Injectable Collagen  
Implantable Craniofacial Prostheses  
Repeat Access Devices for surgical procedures  
Sutures

**General Hospital**

Implantable Vascular Access Devices (Ports) - if new routes of administration or new design  
Infusion Pumps (implantable and closed-loop - depending on the infused drug)

**Neurological**

Electroconvulsive Therapy (ECT) Devices  
Hydrocephalus Shunts  
Implanted Intracerebral/Subcortical Stimulators  
Implanted Intracranial Pressure Monitors  
Implanted Spinal Cord and Nerve Stimulators and Electrodes

**Obstetrics and Gynecology**

Antepartum Home Monitors for Non-Stress Tests  
Antepartum Home Uterine Activity Monitors  
Catheters for Chorionic Villus Sampling (CVS)  
Catheters Introduced into the Fallopian Tubes  
Cervical Dilatation Devices

*Contraceptive Devices:*

- Cervical Caps
- Condoms (for men) made from new materials (e.g., polyurethane)
- Contraceptive *In Vitro* Diagnostics (IVDs)
- Diaphragms
- Female Condoms
- Intrauterine Devices (IUDs)
- New Electrosurgical Instruments for Tubal Coagulation
- New Devices for Occlusion of the Vas Deferens
- Sponges
- Tubal Occlusion Devices (Bands or Clips)

Devices to Prevent Post-op Pelvic Adhesions  
Embryoscopes and Devices intended for fetal surgery  
Falloposcopes and Falloposcopic Delivery Systems  
Intrapartum Fetal Monitors using new physiological markers  
New Devices to Facilitate Assisted Vaginal Delivery  
Thermal Systems for Endometrial Ablation

**Ophthalmics**

Class III Ophthalmic Lasers  
Contact Lens Solutions intended for direct instillation (e.g., lubrication/rewetting solutions) in the eye using new active agents or preservatives with no history of prior ophthalmic/contact lens use or not generally recognized as safe for ophthalmic use  
Corneal Implants  
Corneal Storage Media  
Epikeratophakia Lenticules  
Extended Wear Contact Lens

Eye Valve Implants (glaucoma implant)  
Intraocular Lenses (IOLs) [21 CFR part 813]  
Keratoprotheses Retinal Reattachment Systems: fluids, gases, perfluorocarbons, perfluoropropane, silicone oil, sulfur hexafluoride, tacks  
Viscosurgical Fluids

**Orthopedics and Restorative**

Bone Growth Stimulators  
Calcium Tri-Phosphate Hydroxyapatite  
Ceramics Collagen and Bone Morphogenic Protein Meniscus Replacements  
Implantable Prostheses (ligament, tendon, hip, knee, finger)  
Computer Guided Robotic Surgery

**Radiology**

Boron Neutron Capture Therapy  
Hyperthermia Systems and Applicators

Your comments and suggestions for additional examples are welcome and should be sent to:

*Program Operation Staff (HFZ-403)  
Office of Device Evaluation  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Blvd.  
Rockville, MD 20850  
(301) 594-1190*

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**Emergency Use of Unapproved Medical Devices**

For the purpose of this information sheet, an unapproved medical device is defined as a device that is used for a purpose or condition for which the device requires, but does not have, an approved application for premarket approval under section 515 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360(e)]. An unapproved device may be used in human subjects only if it is approved for clinical testing under an approved application for an Investigational Device Exemption (IDE) under section 520(g) of the Act [21 U.S.C. 360(j)(g)] and 21 CFR part 812. Medical devices that have not received marketing clearance under section 510(k) of the FD&C Act are also considered unapproved devices which require an IDE.

The Food and Drug Administration (FDA) recognizes that emergencies arise where an unapproved device may offer the only possible life-saving alternative, but an IDE for the device does not exist, or the proposed use is not approved under an existing IDE, or the physician or institution is not approved under the IDE. Using its enforcement discretion, FDA has not objected if a physician chooses to use an unapproved device in such an emergency, provided that the physician later justifies to FDA that an emergency actually existed.

**Requirements for Emergency Use**

Each of the following conditions must exist to justify emergency use:

1. the patient is in a life-threatening condition that needs immediate treatment;
2. no generally acceptable alternative for treating the patient is available; and

3. because of the immediate need to use the device, there is no time to use existing procedures to get FDA approval for the use.

FDA expects the physician to determine whether these criteria have been met, to assess the potential for benefits from the unapproved use of the device, and to have substantial reason to believe that benefits will exist. The physician may not conclude that an "emergency" exists in advance of the time when treatment may be needed based solely on the expectation that IDE approval procedures may require more time than is available. Physicians should be aware that FDA expects them to exercise reasonable foresight with respect to potential emergencies and to make appropriate arrangements under the IDE procedures far enough in advance to avoid creating a situation in which such arrangements are impracticable.

In the event that a device is to be used in circumstances meeting the criteria listed above, the device developer should notify the Center for Devices and Radiological Health (CDRH), Program Operation Staff by telephone (301-594-1190) immediately after shipment is made. [Note: an unapproved device may not be shipped in anticipation of an emergency.] Nights and weekends, contact the FDA Office of Emergency Operations (HFA-615) 301-443-1240.

FDA would expect the physician to follow as many subject protection procedures as possible. These include:

1. obtaining an independent assessment by an uninvolved physician;
2. obtaining informed consent from the patient or a legal representative;
3. notifying institutional officials as specified by institutional policies;
4. notifying the Institutional Review Board (IRB); and
5. obtaining authorization from the IDE holder, if an approved IDE for the device exists.

#### After-use Procedures

After an unapproved device is used in an emergency, the physician should:

1. report to the IRB within five days [21 CFR 56.104(c)] and otherwise comply with provisions of the IRB regulations [21 CFR part 56];
2. evaluate the likelihood of a similar need for the device occurring again, and if future use is likely, immediately initiate efforts to obtain IRB approval and an approved IDE for the device's subsequent use; and
3. if an IDE for the use does exist, notify the sponsor of the emergency use, or if an IDE does not exist, notify FDA of the emergency use (CDRH Program Operation Staff 301-594-1190) and provide FDA with a written summary of the conditions constituting the emergency, subject protection measures, and results.

Subsequent emergency use of the device may not occur unless the physician or another person obtains approval of an IDE for the device and its use. If an IDE application for subsequent use has been filed with FDA and FDA disapproves the IDE application, the device may not be used even if the circumstances constituting an emergency exist. Developers of devices that could be used in emergencies should anticipate the likelihood of emergency use and should obtain an approved IDE for such uses.

#### **Exception From Informed Consent Requirement**

Even for an emergency use, the investigator is required to obtain informed consent of the subject or the subject's legally authorized representative unless both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following [21 CFR 50.23(a)]:

- (1) The subject is confronted by a life-threatening situation necessitating the use of the test article.
- (2) Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject.
- (3) Time is not sufficient to obtain consent from the subject's legal representative.
- (4) No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life.

If, in the investigator's opinion, immediate use of the test article is required to preserve the subject's life, and if time is not sufficient to obtain an independent physician's determination that the four conditions above apply, the clinical investigator should make the determination and, within 5 working days after the use of the article, have the determination reviewed and evaluated in writing by a physician who is not participating in the clinical investigation. The investigator must notify the IRB within 5 working days after the use of the test article [21 CFR 50.23(c)].

### **Exception from Informed Consent for Planned Emergency Research**

The conduct of planned research in life-threatening emergent situations where obtaining prospective informed consent has been waived, is provided by 21 CFR 50.24. The research plan must be approved in advance by FDA and the IRB, and publicly disclosed to the community in which the research will be conducted. Such studies are usually not eligible for the emergency approvals described above. The information sheet "Exception from Informed Consent for Studies Conducted in Emergency Settings: Regulatory Language and Excerpts from Preamble," is a compilation of the wording of 21 CFR 50.24 and pertinent portions of the preamble from the October 2, 1996 Federal Register.

*Also see these FDA Information Sheets:*

["Exception from Informed Consent for Studies Conducted in Emergency Settings: Regulatory Language and Excerpts from Preamble"](#)

["Emergency Use of an Investigational Drug or Biologic"](#)

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