



UIC Technology Corner

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An Overview of the FDA Process for Inventors of Medical Devices

Many new inventions are brought to the marketplace every day and one of the more prolific areas is that of medical devices. If the invention is a medical device, however, Food and Drug Administration ("FDA") approval is required prior to marketing. This article will briefly outline some of the procedures that are required to successfully market an FDA-regulated product in the United States.

HISTORY

Medical devices are generally defined as "instruments or contrivances" that are intended to cure, prevent, or mitigate a condition or disease or affect the structure or function of the body but not accomplish this through metabolism or chemical action.¹ Devices, depending on their nature, are categorized into three groups, Class I, Class II and Class III.² A Class I medical device is one where general controls, such as registration of the company and listing the device with the FDA³ and compliance with the Quality System Regulations,⁴ are sufficient to assure that the device will be safe and effective

¹ 21 U.S.C. 321(h)
² 21 U.S.C. 360c(a)
³ 21 U.S.C. 360 requires all

medical device manufacturers to register with the FDA its name and place of business and to identify (list) all medical devices manufactured at that facility.

⁴ The Quality System Regulations ("QSR") 21 C.F.R. 820 et. seq. were formerly known as the Good Manufacturing Practice regulations and generally establish the type of manufacturing controls that are necessary to manufacture medical devices.

for its intended use. Examples of a Class I device include toothbrushes, manual surgical instruments, and examination gloves. A Class II device is one where general controls are insufficient by themselves but that sufficient information about the device is known that Special Controls⁵ are able to be created. Examples are a cardiac pressure monitor, an infusion pump and powered surgical instruments. A Class III device is one where general and Special Controls are insufficient to assure safety and effectiveness. Examples include heart valves, pacemakers, and bone growth stimulators. For some Class I and all Class II and III medical devices to be legally marketed in the United States, it is required that FDA review documentation and authorize such marketing.

In 1976, Congress amended the federal Food, Drug, and Cosmetic Act (the "Act") to require FDA review of medical devices prior to marketing of the device. Prior to this time, medical devices were controlled by FDA but pre-market review was not required. The system instituted by Congress required FDA to review all "new" medical devices to assure that the device was both safe and effective for the intended use and was referred to as the Pre-Market Approval ("PMA") process. It was Congress' intent to only require premarket review for "new" devices and, unlike the Drug Amendments in 1962⁶, not require

⁵ Special Controls may include standards, post-approval surveillance or testing, patent registers or other established controls.

⁶ In 1962, Congress amended the Act to require a showing of efficacy as well as safety for all pharmaceutical products. Included in the amendment

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safety or efficacy review of product already on the market. To assure that all "new" devices were undergoing the PMA process, Congress also created the 510(k) premarket notification process where a device that was introduced to the market for the first time would be reviewed by FDA to determine if the device was "new" and therefore require to proceed through the PMA process. Unless a device was substantially similar to a device that was legally on the market before 1976, it was considered "new". This substantial similarity concept was subsequently codified in 1990 and the term for comparison of the two devices is now "substantial equivalence".⁷ The notification process has changed over the years and now authorization from the FDA for 510(k) devices is also required.

The review process can take two forms. The first form of review is a substantial and comprehensive review of the safety and effectiveness of the medical device. This process is called a pre-market approval ("PMA") process and is applied to all Class III devices. The second process which is generally quicker and less costly (and which about 99.8% of the medical devices go through) is referred to as a 510(k) process. The 510(k) process is required for some Class I and most Class II devices.⁸ Finally, at times, through either of the two processes, individuals seeking FDA authorization may need to perform clinical tests on human subjects with the medical device to demonstrate its safety and effectiveness. In order to conduct such testing, again prior authorization is required from FDA, referred to as the Investigational Device Exemption ("IDE") process.

The PMA

The PMA process is required for all medical devices that either treat a new disease or condition or that accomplish treatments in a new manner. For these devices it is necessary for the individual seeking authorization, the Sponsor, to demonstrate through an application filed with the FDA that the product is both safe and effective for its intended use. This application must contain information about not only the design and method of manufacturer of the medical device but also the clinical study results, the sources of the component parts, the test procedures that are performed both in-process and on the finished product, a comprehensive literature search of

applicable and related technologies and all other information that may impact the determination of safety and efficacy by the FDA.⁹ The compilation of the PMA takes months to accomplish and the current FDA review time is approximately twelve months. In general, this means that even after the clinical studies are complete, the product would not be available to market for an additional 18 months.

The IDE

The main portion of the PMA, as discussed above, is the result of the human clinical study that is conducted to show safety and effectiveness. In order to conduct testing of a medical device on human subjects to support a PMA, it is probable that the Sponsor of the PMA will need to obtain FDA authority prior to conducting the studies. The purpose of the IDE submission is to give sufficient information to FDA to determine that the clinical studies should be conducted.

There are two elements that are reviewed by FDA. First, the information submitted in the IDE must demonstrate that the use of the medical device on humans is generally safe. This safety review includes a balancing of the risk of using the device against the potential benefit of its use considering the disease. Included in the safety reviewed is the review of the informed consent as well as the conclusion of the Ethics Review Board, also known as the Institutional Review Board ("IRB"). No proof of efficacy is given in the IDE, as that is the purpose of the clinical study.

The second element of the IDE is the protocol. The question that is asked is whether the data that is anticipated to be obtained through conducting the clinical study will result in the ability to make the determination of efficacy of the product. This review looks at the study structure, the statistics, the clinical endpoints and other aspects of the clinical protocol with the intent to assure that meaningful data will be collected through the process.

While most studies involving Class III devices will require an IDE, many studies involving Class I or Class II devices may not. The investigational device exemption regulations¹⁰ describes two types of devices' studies, "significant risk" ("SR") and "non-significant risk" ("NSR"). An SR device study is defined¹¹ as a study of a device that presents the potential for serious risk to the health, safety or welfare of the subject and is (1) an implant or (2) is

used in supporting or sustaining life. An NSR device investigation is one that does not meet the definition for significant risk studies. Significant risk device studies require IDE submission and approval wherein non-significant risk device studies have fewer regulatory controls and FDA authorization through the IDE process is not required. For both types of studies, IRB approval as well as informed consent and other patient protection measures are required.

The 510(k) Process

The more common review process that is utilized for a majority of the medical devices brought to market is known as the 510(k) process. This process is less expensive and allows devices eligible to get to market quicker, usually in 3-6 months. This is not an approval process but rather a notification process where FDA is notified that a new device is going to be introduced into the market and that the new device is "substantially equivalent" to a non-PMA device already on the market. This "old" medical device is known as the predicate product. It is important to note that the standards that are used to determine "newness" for patent purposes are different than the standard used by the FDA. A "new" device may be able to receive a patent due to a unique feature but at the same time be "substantially equivalent" to a predicate product.

For a new device to be substantially equivalent to the predicate product it is necessary to meet two criteria. First it is necessary that the devices have the same intended use. If a predicate product cannot be found with the same intended use, then the products cannot be determined to be substantially equivalent and a PMA will be required for the "new" device. The second criteria is that the two devices must have the same technological characteristics or if the technological characteristics differ; no new questions of safety or efficacy are raised by this difference. Essentially, the "new" product must, (1) do the same thing, (2) in generally the same way as the predicate product.

If the products do not utilize the same technological characteristics, then it may be necessary to supplement the 510(k) application with data that shows that there are no new issues of safety or effectiveness. This new data can take the form of bench testing, in-vitro testing or human clinical trials. If human clinical trials are necessary, the same elements as listed above for the IDE process come into play.

In conclusion, if the invention being developed is a medical device, not only will its inventor need to deal with the Patent Office but, to sell the device, will

⁷ 21 U.S.C 360c(i)

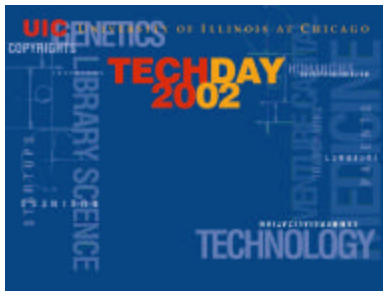
⁸ Through regulation, most Class I and some Class II devices have been determined exempt from the 510(k) process.

⁹ See generally 21 CFR Part

814

¹⁰ 21 C.F.R., Part 812

¹¹ 21 C.F.R. 812.3(m)



TechDay 2002

? This is an annual free symposium that attracts an audience from the public, private, and government sector.

It will be held at the Chicago Illini Union, 828 S. Wolcott Ave., Chicago Rooms A,B & C.

It will commence at 1:00PM on Wednesday, April 3, 2002 and has as its theme-“ Feng Shui your IP”.

The Inventor of the Year Award Celebration and Networking event begin at 5:00 PM.

Refreshments will be served. Phone 312 996-7018 to register for this event.

? The Inventor of the Year Award will follow the TechDay Symposium.

This event honors UIC faculty or staff who have been nominated and completed a selection process through the Intellectual Property Advisory Committee. A Call for Nominations follows.

Past Inventors of the Year:

2000

Dr. David E. Boyce
 Dr. Ananda M. Chakrabarty
 Dr. Thomas A. De. Fanti
 Dr. Norman R. Farnsworth
 Dr. John M. Pezzuto
 Dr. Charles K. Rhodes
 Dr. Igor B. Roninson
 Daniel J. Sandin

2001

Faydor L. Litvin

A CALL FOR NOMINATIONS FOR UIC's INVENTOR OF THE YEAR 2002

Nominations for UIC's Inventor of the Year 2002 are now being received by UIC's Office of Technology Management. Nominations can be submitted by anyone from the UIC community who is knowledgeable about a successful UIC inventor. Self-nominations will be accepted.

A nominee is eligible for nomination when the following criteria are satisfied:

1. The nominee must be a full-time UIC faculty or staff member;
2. The nominee must be a primary inventor or creator of a University of Illinois at Chicago technology which is patented or copyrighted and for which significant research effort conducted at UIC contributed to the advancement of knowledge in the field; and
3. The technology has been developed into a product or process that has had or shows significant potential for benefit to society.

Any information disclosed during the nomination process will be considered confidential and will be used only for Inventor of the Year Award 2002 review and nomination purposes by UIC's Office of Technology Management, the UIC Intellectual Property Advisory Committee and the Vice Chancellor for Research who will determine the awardee.

Nomination Form Information Required:

Name
College/Dept
Phone/Fax /E-mail

Description of candidate's inventiveness; his/her inventive accomplishments and their impact upon and benefit to society (500 words or less).

Candidate's curriculum vitae or resume.

Documentation of candidate's patent(s). If more than five, list only patent numbers, titles, and issue dates.

Name of Nominating Individual
Phone/Fax/E-Mail

Optional:

-Three letters supporting the candidate's nomination from individuals other than the Nominator. Recommenders must be within the candidate's field but outside the candidate's current professional or academic affiliation. Each letter of recommendation must be accompanied by address, telephone and fax numbers, email address and a brief description of the Recommender's affiliation with the candidate.

- No more than ten pages of other materials supporting the candidate's achievements, such as professional articles and press clippings.

A nomination must be submitted in writing to the UIC Office of Technology Management by 5:00 PM on February 28, 2002. The awardee of UIC's Inventor of the Year 2002 will be announced at the UIC TechDay 2002 Symposium, in April 2002.



For further information on the technology transfer process at University of Illinois, contact the Office of Technology Management (312) 996-7018, or visit the [OTM website](#).

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