



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2001

Given Imaging, Ltd.
c/o Mr. Jonathan S. Kahan
Hogan & Hartson, L.L.P.
Columbia Square
555 Thirteenth Street, N.W.
Washington, D.C. 20004-1109

Re: K010312
Evaluation of Class III Designation (deNovo)
Given® Diagnostic Imaging System
Dated: June 11, 2001
Received: June 11, 2001
21 CFR §876.1300/Product Code: 78 NEZ
Regulatory Class: Class II

Dear Mr. Kahan,

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for classification of the Given® Diagnostic Imaging System that is intended for visualization of the small bowel mucosa as an adjunctive tool in the detection of abnormalities of the small bowel.

FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Given® Diagnostic Imaging System, and substantially equivalent devices of this generic type into class II under the generic name, Ingestible Telemetric Gastrointestinal Capsule Imaging System. This order also identifies the special controls applicable to this device.

FDA identifies this generic type of device as: An Ingestible Telemetric Gastrointestinal Capsule Imaging System is used for visualization of the small bowel mucosa as an adjunctive tool in the detection of abnormalities of the small bowel. The device captures images of the small bowel with a wireless camera contained in a capsule. This device includes an ingestible capsule (containing a light source, camera, transmitter, and battery), an antenna array, a receiving/recording unit, a data storage device, computer software to process the images, and accessories.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as post-amendments devices, are classified automatically by statute into class III without any FDA rulemaking process.

These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register classifying the device.

On June 11, 2001, FDA filed your petition requesting classification of the Given® Diagnostic Imaging System into class II. The petition was submitted under section 513(f)(2) of the act. In accordance with section 513(f)(1) of the act, FDA issued an order on June 11, 2001, automatically classifying the (device) in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, which was subsequently reclassified into class I or class II. In order to classify the Given® Diagnostic Imaging System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the petition, including the 510(k) submission K010312, FDA has determined that the Given® Diagnostic Imaging System intended for visualization of the small bowel mucosa as an adjunctive tool in the detection of abnormalities of the small bowel, can be classified in class II with the establishment of special controls. FDA believes that class II special controls along with the general controls of the act, provide reasonable assurance of the safety and effectiveness of the device. Therefore, in addition to the general controls of the act, the Given® Diagnostic Imaging System is subject to the following special controls: *Class II Special Controls Guidance Document: Ingestible Telemetric Gastrointestinal Capsule Imaging System.*

The Class II Special Controls Guidance Document identifies the potential risks presented by the device:

1. Biocompatibility;
2. Electrical safety;
3. Electromagnetic interference with this and other medical devices, and radiofrequency propagation transmission power;
4. Environmental interference with image acquisition;
5. Functional reliability;
6. Intestinal obstruction or injury; and,
7. Misinterpretation of the captured images.

FDA believes the following controls identified in the Class II Special Controls Guidance Document, when combined with the general controls of the act, will provide reasonable assurance of the safety and effectiveness of this type device:

1. Prescription labeling in accordance with 21 CFR §801.109;
2. Patient labeling;
3. Physician labeling;
4. Biocompatibility testing as outlined in the FDA-modified "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing.
5. Performance information to address safety and effectiveness issues related to device design. This should include clinical information about safety and effectiveness and, if appropriate, safety data from animal studies;
6. Bench testing;
7. Sufficient evidence of performance for software-controlled medical devices. The degree of evidence is described in the FDA guidance document titled "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

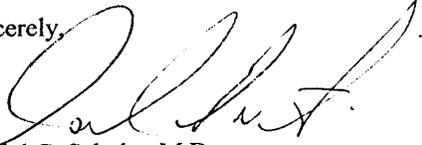
Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements. Thus, persons who intend to market this device must submit to FDA a premarket notification submission containing information on the Ingestible telemetric gastrointestinal capsule imaging system they intend to market and receive clearance from FDA prior to marketing the device.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market this device, subject to the general control provisions of the Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Carolyn Neuland, Ph.D. at (301) 594-1220.

Sincerely,



Daniel G. Schultz, M.D.
Deputy Director, Clinical and
Review Policy
Office of Device Evaluation
Center for Devices and Radiological Health