Class II Special Controls Guidance Document: Ingestible Telemetric Gastrointestinal Capsule Imaging System; Final Guidance for Industry and FDA

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U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Gastroenterology and Renal Devices Branch
Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

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This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

Background

On August 1, 2001, FDA reclassified ingestible capsule wireless gastrointestinal imaging system from Class III designation to Class II. This guidance document describes a means by which ingestible capsule wireless gastrointestinal imaging system devices may comply with the requirements of class II special controls. Designation of this guidance document as a special control means that manufacturers of an ingestible telemetric gastrointestinal capsule imaging system, who follow the recommendations listed in this document before introducing their device into commercial distribution in the United States, will be able to market their device after they have submitted a premarket notification submission, referred to as a 510(k), and received a finding of "substantial equivalence" for their device. Manufacturers should comply with either the recommendations of this guidance or some alternate means that provide equivalent assurance of safety and effectiveness.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to comply with the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

Scope

FDA identifies this generic type of device as an gastroenterology and renal device under 21CFR §876.1300, product code NEZ. This generic type of device, 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.

Risks to Health

FDA has identified risks to health associated with this type of device. These risks involve:

1. Biocompatibility;
2. Electrical and mechanical safety;
3. Radio-frequency (RF) radiated power and electromagnetic compatibility (EMC), including interference with other medical devices and with this device (e.g., interference with image acquisition);
4. Functional reliability, including structural integrity and image acquisition;
5. Intestinal obstruction or injury; and
6. Misinterpretation of the captured images.

Controls

FDA believes the following controls, when combined with the general controls of the act, will provide reasonable assurance of the safety and effectiveness of this type device:

1. The premarket notification must include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). These devices are prescription medical devices, and according to 21 CFR 801.109 must bear the following caution statement: "Caution: Federal law restricts this device to sale by or on the order of a physician."

2. Patient labeling should conform to the "Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers" with instructions that:

    a. describe proper use of the device;

    b. clearly describe dietary instructions before and during the use of the device;

    c. clearly identify any limitations in physical activity during the use of the device;

d. clearly identify all device safety features and limits to its use;

e. describe all relevant warnings, precautions, contraindications, and risks of the device;

f. explain that the patient's physician should be consulted for any symptoms of abdominal pain, nausea, or vomiting;

g. address the issue of electromagnetic interference (EMI) which may cause loss of images (e.g., from Magnetic Resonance Imaging (MRI), other in-band RF transmitters such as amateur radio); and

h. clearly describe sources of electromagnetic energy the patient should avoid proximity to during the use of the device (e.g., MRI, airport security devices).

3. Physician labeling should include instructions that:

a. describe proper use of the device including correct placement of the antenna array;

b. identify all device safety features and limits to its use;

c. document all contraindications which may include:

i. patients with cardiac pacemakers or other implanted electronic devices;

ii. patients with known intestinal obstruction or significant intestinal strictures;

d. describe all relevant warnings, precautions, and risks of the device, which may include the following;

i. The physician should consider performing a contrasted x-ray series in patients with suspected strictures or fistulas prior to using this device;

ii. Variations in individual patient GI motility may decrease the length of the small bowel that is imaged;

e. describe correct storage for the device prior to being used;

f. address the issue of electromagnetic interference which may cause loss of images (e.g., from MRI, other in-band RF transmitters such as amateur radio);

g. address the experience needed by the physician to correctly interpret the acquired images;

h. address any ancillary diagnostic tests or examinations that should be performed prior to or in conjunction with this device;

i. address the limits of the technology based on clinical studies and bench testing; and

j. summarize the results of clinical studies.

4. Biocompatibility testing should be performed as outlined in the FDA-modified "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing" http://www.fda.gov/cdrh/g951.html for a surface device that contacts breached or compromised surfaces for prolonged contact.

5. Bench testing should include the following:

   a. Evidence should be submitted to evaluate the mechanical and structural integrity of the device system when subjected to clinical use conditions. This testing should include the following:

      i. evaluation of the device system when exposed to a range of pH levels for the period of time that the device will be used;

      ii. mechanical integrity test, as needed, to evaluate the strength of the device system when subjected to mechanical forces that may be expected during clinical usage;

      iii. battery life; and

      iv. field of view and depth of focus.

   b. Evidence should be submitted to evaluate the electrical and mechanical safety, RF radiated power, and EMC of the device system. EMC testing should specifically consider the environment in which the device system may be used. Standards such as IEC 60601-1 and IEC 60601-1-2 should be used to guide test selection. Radio transmitters and receivers should also be in compliance with national radio regulations.

6. Software testing should be included to show the device performs correctly.

   Sufficient evidence of performance is needed for software-controlled medical devices. The degree of evidence needed is determined by the "level of concern" described in the FDA guidance document titled "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" http://www.fda.gov/cdrh/ode/57.html. The "level of concern" is related to the outcome of software failure and may be minor, moderate, or major. The software for this device is generally considered a "minor level of concern" as defined in the Software guidance.

Overall, the documentation related to the software contained in the medical device should provide sufficient evidence to describe the role of the software included in the device, and performance testing to demonstrate that the software functions as designed.

7. Performance information should address safety and effectiveness issues related to device design. This should include, if appropriate, safety data from animal studies. Clinical information about safety and effectiveness should be included. The information should address:

    a. ease of device ingestion;

    b. intestinal transit time (time between ingestion and excretion);

    c. documentation of excretion/recovery;

    d. diagnostic yield when compared to other standard mucosal imaging procedures (upper endoscopy, enteroscopy, colonoscopy);

    e. adverse events during and following the use of the device; and

    f. agreement between two or more reviewers with respect to interpretation of the images obtained.

Premarket Notification Requirements

FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of this generic type of device, and therefore, the device type is not exempt from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act. Thus, persons who intend to market a device of this type need to submit a premarket notification to FDA and receive agency clearance prior to marketing the device.

An Abbreviated 510(k) that relies on a Class II Special Controls Guidance Document should contain the following.

- a coversheet prominently identifying the submission as an Abbreviated 510(k) and citing the title of this Guidance Document;

- items required under 21 CFR 807.87, including a description of the device (including detailed, labeled drawings and a compete discussion of the performance specifications), the intended use of the device, and the proposed labeling for the device.

- a summary report that describes how this Class II Special Controls Guidance Document was used to address the risks associated with this particular device type. You should describe your device performance requirements and discuss the hardware

and software functions provided to address the risks identified in this guidance document, as well as any additional risks identified in your risk analysis. For each performance aspect identified in sections 5 through 7 of this Special Controls Guidance document, the summary report should briefly discuss each test method used, the acceptance criteria applied, and the test results achieved. If a manufacturer elects to use an alternative approach to address a particular risk, sufficient detail should be provided to justify the alternative approach. If any part of the device design or testing relies on a recognized standard, the summary report should include: (1) a statement that testing will be conducted and meet specified acceptance criteria before the product is marketed, or (2) a declaration of conformity to the standard. **[Note: Testing must be completed before submitting a declaration of conformity to a recognized standard.]**

- Indications for Use enclosure.

The following is a table of the controls that address the identified risks to health:

Risk	**Reference to Controls in This Document**
(1) Biocompatibility;	4.
(2) Electrical and mechanical safety;	5.a., b.
(3) RF radiated power and EMC, including interference with other medical devices and with this device (e.g., interference with image acquisition);	2.g., 2.h., 3.f., 5.b.
(4) Functional reliability,	3.a.b.c.d.e., 5.a.b., 6.
(5) Intestinal obstruction or injury; and	1., 2.a.b.c.d.e.f., 3.h., 7.a.b.c.d.e.
(6) Misinterpretation of the captured images.	3.g.i.j., 7.f.