



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 29 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. A.R. Hoenninger
Managing Director C3SG
11103 San Pedro, Suite 117
San Antonio, Texas 78216

Re: Reclassification of Colonic Irrigation Devices
Dated: March 15, 2001

Dear Mr. Hoenninger:

The Food and Drug Administration has reviewed the above referenced petition for reclassification pursuant to section 513(f)(2)(A) of the Federal Food, Drug and Cosmetic Act (Act) and has determined the petition is administratively incomplete and therefore cannot be filed.

This petition does not include an adequate description of the major risks to health of the device, or a summary of all safety and effectiveness data supporting the recommended classification (i.e., a textual and tabular summary of clinical results of the significant published clinical studies), or a justification for your proposed classification based on a comparative analysis of the known risks to health and the available scientific evidence in support of safety and effectiveness. In addition, the petition not only fails to identify general and special controls which would apply to colonic irrigation systems as a Class II device, but provides no evidence to support that these controls would ensure the safety and effectiveness of the device for the intended uses.

Please note that the regulations governing reclassification of medical devices are included in the Medical Device Classification Procedures, Part 860 of Title 21, Code of Federal Regulations (21 CFR 860). Reclassification is specifically addressed in Subpart C, sections 860.120 through 860.136.

A copy of Part 860 is enclosed with this letter. Note that the definitions in section 860.3, the discussion of confidentiality and filing in section 860.5, the discussion of determination of safety and effectiveness and of valid scientific evidence in section 860.7, and the discussion of content and form in section 860.123, all bear directly on petitions for reclassification and should be well understood by all petitioners.

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Should you choose to resubmit a petition in the future, the following components should be included in the submission:

1. Any subsequent submission should clearly and accurately state the action which is requested. The subject devices are currently classified as Class II when intended for colon cleansing when medically indicated, such as before radiological or endoscopic examinations, and Class III when intended for other uses. The reclassification petition you submitted (Tab 2, Section 2) stated that you were petitioning the FDA to change the classification for the colonic irrigation systems (including speculums and rectal nozzles) "from Class II to class III."
2. A complete and thorough description of the device-type should be provided in any future submission and include:
 - a. Background information.
 - i. a description of the purpose of colonic irrigation systems;
 - ii. a brief discussion of colonic anatomy and function; and
 - iii. a complete summary of all devices currently available which highlights similarities and differences.
 - b. Specific Indications for Use.
 - c. Complete description of the type of device to be reclassified, including:
 - i. the number of components which form the device system;
 - ii. a description of each components' physical property including diagrams where possible;
 - iii. a functional description of each component;
 - iv. a description of the interconnection mechanism between components;
 - v. a discussion of overall device-type function;
 - vi. a discussion of how the devices are disinfected and what components are disposable; and
 - vii. a summary of mechanical testing which includes data demonstrating that the device:
 - terminates function when water temperature exceeds 104°F;
 - terminates function when intracolonic pressure exceeds 2 psi;
 - can be cleaned of all disinfectant; and
 - complies with electrical standards.
3. Please be advised that reclassification applies not only to specific devices but rather to a generic type of devices which share common characteristics. Reclassification to Class II would apply to the marketing of all colonic irrigation systems, not only those from the

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five specific manufacturers that you have listed. This concept should be incorporated within any future submission.

4. The reclassification petition (Tabs 4-7) describes a multitude of medical conditions and indications for which the device may be used. No valid scientific evidence, however, is provided to support the clinical benefit or utility of colonic irrigation systems in the treatment of any of these diseases or disorders. Any future submission should clearly state which of the indications are intended for reclassification from Class III to Class II. In addition, the specific clinical aspects of “general well being” for which you are requesting down-classification should be defined. For each of these indications, you must submit valid clinical data to support these claims. This should include summaries from well-controlled clinical investigations performed (in the United States or abroad) to evaluate the safety and effectiveness of the device for that specific indicated use. If you are unaware of any such data, you should consider designing and conducting such studies under significant-risk IDE status. You may wish to consider contacting the National Center for Complementary and Alternative Medicine of the National Institute of Health (www.nccam.nih.gov) for assistance in performing such studies. The data supplied in your submission is incomplete and based on unsubstantiated opinions. The FDA does not consider this type of information to be valid scientific evidence per 21 CFR 860.7.
5. A reclassification petition must demonstrate that the risks previously identified for a Class III device, in light of new information, can be adequately addressed by either general or special controls. When the device was originally classified by the Gastroenterology-Urology Classification Panel (Federal Register, January 23, 1981), several risks to health were identified. These risks, which the Panel felt could not be controlled by general or specific controls, became the basis for classifying this device as class III. The risks noted were:
 - tissue burns from water overheating;
 - perforation of the colon;
 - colon irritation; and
 - electrical injury.

Any future submission should address, at a minimum, the above risks to health as well as the risk of infection. A summary and analysis of all safety data supporting the recommended classification should be provided, as well as a listing of Medical Device Reports (MDRs) and a summary of published adverse events. In addition, evidence should be provided to be able to conclude that the identified risks are mitigated by new information or controlled by general/special controls. Each control should be described in a detailed manner.

The submission of information that addresses the issues noted above should allow us to file your reclassification petition, allow adequate information for a substantive review, and allow us to refer it to the appropriate advisory panel for their review and recommendation. Any further

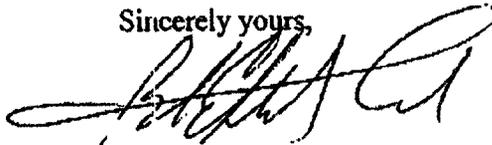
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correspondence pertaining to this petition should reference the above reclassification petition number and be submitted with a minimum of 5 copies.

If you have questions concerning the contents of this letter, please contact Ms. Kathleen Olvey at (301) 594-1220. We strongly suggest that you call to schedule either a meeting or teleconference to discuss your petition prior to re-submission.

If you need information or assistance concerning the reclassification regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosures