DRAFT GUIDANCE FOR THE PREPARATION OF A PREMARKET NOTIFICATION FOR EXTENDED LAPAROSCOPY DEVICES (ELD)

August 30, 1994
(reformatted 12/17/97)

This guidance document may contain references to addresses and telephone numbers that are now obsolete. The following contact information is to be used instead:

- **While this guidance document represents a final document, comments and suggestions may be submitted at any time for Agency consideration to the General Surgical Devices Branch, 9200 Corporate Blvd., HFZ-410, Rockville, MD 20850.**
- **For questions regarding the use or interpretation of this guidance, contact the General Surgical Devices Branch at 301- 594-1307.**
- **To contact the Division of Small Manufacturers Assistance (DSMA), call 800-638-2041 or 301-443-6597; fax 301-443-8818; email dsmo@cdrh.fda.gov; or write to DSMA (HFZ-200), Food and Drug Administration, 1350 Piccard Drive, Rockville, Maryland 20850-4307. FACTS-ON-DEMAND (800-899-0381 or 301-827-0111) and the World Wide Web (CDRH home page: http://www.fda.gov/cdrh/index.html) also provide easy access to the latest information and operating policies and procedures.**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, MD 20850

I. PURPOSE:

This guidance provides information for the preparation of a Premarket Notification (510(k)) for an emerging group of devices that does have a readily identifiable predicate with which to establish substantial equivalence, but does fall into a category of laparoscopic accessories for which a discernible pattern of clinical and technological progress is apparent, thus rendering them appropriate for 510(k) review. These devices will subsequently be referred to as Extended Laparoscopy Devices (ELD). They are Class II devices and, therefore, subject to special controls under Section 513 of the Federal Food, Drug, and Cosmetic Act. Determination of substantial equivalence will be made based upon analysis of data designed to establish that the new device is "as safe and effective as a legally marketed device." While the exact nature and extent of information necessary to determine substantial equivalence for an ELD will be evaluated individually based upon the specific device and labeling claims requested, it is our goal in this communication to present an outline of what we would consider reasonable parameters which would allow for comprehensive and expeditious review of your submission.

II. DEFINITION:

An Extended Laparoscopy Device (ELD) is any device that provides extracorporeal extension of pneumoperitoneum and/or permits the surgeon to perform tasks in a manner normally ascribed to open surgery within the field of pneumoperitoneum, e.g., tactile contact or use of standard manual surgical instruments.

III. GENERAL INFORMATION:

1. Product names; trade and usual
2. Classification; Class II, 78GCJ
3. Purpose of submission, CFR 807.81
4. Predicate; may use combination of devices for intended use technical criteria

IV. LABELING:

The proposed labeling should include labels and advertisements with descriptions, intended use, directions for use and appropriate warnings and cautions. A statement must be included that advises the user to be adequately trained in each of the three approaches; laparoscopic, laparoscopic-assisted, and open surgery. Any claims related to enhanced efficacy or ease of use relative to standard laparoscopic or open surgery must be substantiated with appropriate clinical data.

V. MATERIALS:

This section requires a complete listing of all materials used in fabricating the device. We ask that you compare and contrast all materials with those of the predicate device and that you provide biocompatibility data for those materials that are not identifiable in a legally marketed predicate device according to the ISO 10993 standard.

VI. STERILITY:

For a device sold sterile, provide the following information as detailed in the ODE Blue Book Memorandum #K90-1:

1. Sterilization method
2. Validation method
3. Sterility assurance level (SAL)- must be 10^{-6}
4. Packaging information

VII. PERFORMANCE DATA:

Due to the novel features displayed by these products and the relative paucity of information concerning the devices themselves and the clinical applications for which they are intended, FDA requires performance testing, including clinical evaluation.

1 . Bench testing must include evidence that each component of device and the device itself possesses the strength to withstand the pressures normally associated with laparoscopic surgery. Integrity of valves and seals during different phases of operation should be analyzed and documented.

2 . Animal testing should be designed to demonstrate compatibility of the device with living tissues and to address to as great degree as possible whether or not the design of the device allows the user to perform currently accepted laparoscopic functions and/or procedures in a safe and effective manner.

3. Clinical studies should be designed to confirm the impressions reached in the first two testing phases. These studies may be undertaken in conjunction with a local IRB without an FDA approved IDE; however, we would be happy to assist the manufacturer in designing a suitable protocol or analyzing preliminary data. In general, we expect these studies to involve two phases:

   a. an initial feasibility phase of 10-20 patients to establish basic product viability and allow for design modifications; and

   b. a second "pivotal" phase of 50-200 patients at sever sites with the goal of developing comparative data for a single procedure with and without the use of ELD to compare device performance to a recognized predicate device and/or procedure. Parameters of interest may include anesthesia time, blood loss, complications, duration of intensive care and hospitalization.

VIII. CONCLUSION:

We hope that this guidance provides an insight to our current thinking regarding this new group of devices. Our goal is to clarify the review process to allow for rapid deployment of this exciting new technology while maintaining the necessary quality standards that physicians and patients deserve.