This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

MAY 17 1993

To: MEDICAL DEVICE INDUSTRY

Subject: ENDOSCOPY AND LAPAROSCOPY ACCESSORIES

The Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) has recently learned that some medical device firms are commercially marketing accessories to endoscopes/laparoscopes without submitting a premarket notification for the accessory, as required by section 510(k) of the Food Drug and Cosmetic Act (the Act). Endoscopes/ laparoscopes have been classified by FDA as class II medical devices.

Title 21, Code of Federal Regulations (21 CFR 876.1500), identifies and classifies endoscopes/laparoscopes and accessories as class II devices. FDA has determined, in accordance with our regulations, that when an accessory to a device is intended to be used with a class II device, then that accessory becomes a class II device and is subject to premarket notification requirements. Examples of devices which are considered accessories to endoscopes/laparoscopes include, but are not limited to cleaning accessories, photographic accessories, binocular attachments, pocket battery boxes, fiberoptic illuminators, lamps, cytology brushes, lubricating jelly for transurethral surgical instruments, and laparoscopic sampling accessories (including probes, scissors, forceps, graspers, and dissectors).

Failure to submit a premarket notification at least ninety (90) days before you propose to introduce the device in interstate commerce is a prohibited act under section 301(p) of the Act, and results in the device being misbranded within the meaning of section 502(o) of the Act. Firms that are currently commercially marketing, promoting, and/or distributing endoscopic/laparoscopic accessories without having submitted a 510(k) notification should take prompt action to correct this violation. Premarket notification submissions (510(k))'s should be submitted to CDRH's Office of Device Evaluation (HFZ-404) at the above address. Continued marketing of accessories for endoscopes/laparoscopes without submission of a 510(k) may result in regulatory action without further notice. These actions include, but are not limited to seizure, injunction, and/or civil penalties.

You are requested to notify this office in writing within thirty (30) working days of receipt of this letter, advising us of the specific steps you have taken to correct this violation. If corrective action, including the submission of a 510(k) premarket notification cannot be completed within thirty (30) working days, state the reason for the delay and the time within which corrections will be completed. A copy of this letter has been sent to the FDA district office in which your firm is located. You should also report any action you take to correct this violation to your local FDA district.

Your response to this letter should be sent to FDA, CDRH, General Surgery Branch, at the above address. Any questions you may have regarding this letter should be directed to Ms. Carol Shirk at 301-427-1116.

Sincerely yours,

Adrianne Galdi

Adrianne Galdi
Acting Director
Division of Enforcement I
Office of Compliance
and Surveillance
Center for Devices
and Radiological Health