

K951173

SUMMARY OF INFORMATION SUPPORTING  
SAFETY AND EFFECTIVENESS:

MAR 24 1995

The subject device is substantially equivalent in safety and effectiveness to the currently marketed AUTO SUTURE\* Endoscopic Suturing Device\*\*, as is evident in the submitted information on design, function, materials, performance and labeling. The devices are equivalent in the following areas:

- Both the subject device and currently marketed devices are indicated for suturing various tissues and structures.
- Both the subject device and other products currently marketed by United States Surgical Corporation are manufactured in the same facilities and with similar processes and controls.
- The subject device is manufactured from biosafe materials that are used in other product currently marketed by United States Surgical Corporation.
- Both the subject device and other products currently marketed by United States Surgical Corporation are packaged in the same facilities, using similar materials, processes and controls.
- Both the subject device and other products currently marketed by United States Surgical Corporation are sterilized in the same facilities, using similar processes and controls.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 24 1995

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20856

Mr. Victor Clavelli  
Associate, Regulatory Affairs  
United States Surgical Corporation  
150 Glover Avenue  
Norwalk, Connecticut 06856

Re: K951173  
Endoscopic Needle Driver  
Regulatory Class: II  
Product Code: GCJ  
Dated: March 13, 1995  
Received: March 15, 1995

Dear Mr. Clavelli:

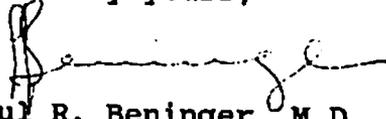
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2- Mr. Victor Clavelli

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice regarding labeling for your device in accordance with 21 CFR Part 801, promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



Paul R. Beninger, M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

