This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: July 30, 1999

510(k) number: K992572

Applicant Information:
NTERO Surgical, Inc.
1137D San Antonio Rd
Palo Alto, CA 94303

Contact Person: D. Bommi Bommannan
Phone Number: (650) 428-1000 ext. 101
Fax Number: (650) 428-0700

Device Information:
Classification: Class II
Trade Name: NTERO RF Sleeve
Classification Name: Electrosurgical Device and accessories (21 CFR 870.4400)

Equivalent Device:
The subject device is substantially equivalent in intended use and/or method of operation to the USSC Versaport Sleeve (K954108), the Surgical Laser SLT Hemosleeve Bipolar Sheath (K984018) and the Dorsal Orthopedic Coagulating Cannula (K953696).

Intended Use:
The NTERO RF Sleeve is intended for use during laparoscopic surgery to maintain a port of entry and to coagulate tissue.

Test Results:
Performance
Results of *in vitro* and *in vivo* testing demonstrate that the NTERO RF Sleeve is safe and effective for its intended function.

Biocompatibility
The materials used in the NTERO Probe have been shown to be biocompatible.

Summary:
Based on the intended use, product, performance and biocompatability information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 24 1999

Mr. D. Bommi Bommannan
President
NTERO Surgical, Inc.
1137D San Antonio Road
Palo Alto, California 94303

Re: K992572
Trade Name: NTERO RF Sleeve
Regulatory Class: II
Product Code: GEI
Dated: July 30, 1999
Received: August 2, 1999

Dear Mr. Bommannan:

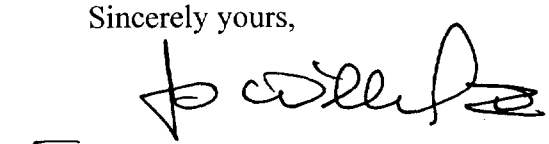
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K992572

Device Name: NTERO RF Sleeve

Indications for Use:

The NTERO RF Sleeve is intended for use during laparoscopic surgery to maintain a port of entry and to coagulate tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992572

Prescription Use ✓ OR Over-the Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)