SUMMARY OF SAFETY AND EFFECTIVENESS
VERRES NEEDLE AND CANNULA

K971837 AUG - 6

The Summary of Safety and Effectiveness on Laparoscopic surgery and the instruments used reflects data available and presented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies may require alterations of the conclusions or recommendations set forth.

Intended Use

Verres Needle and Cannula is intended for use in multiple surgical specialties that utilize minimally invasive surgical procedures to establish pneumoperitoneum and to provide access for operative and diagnostic instrumentation.

Caution

Federal law (USA) restricts this device to sale by or on the order of a physician.

Substantial Equivalency Information

The Verres Needle Cannula is similar to the Gynescope Trocar and Sleeves and the Marlow Verres Needle.

	Gynescope Trocar and Sleeves	**Marlow Verres Needle**	**Verres Needle and Cannula**
Material	Stainless Steel	Stainless Steel	Stainless Steel
Needle	N/A	Spring-Loaded	Spring-Loaded
Diameter	5.0 - 11.5mm	2.0 mm	2.0 - 5.0mm

The intended use and technological characteristics of these devices do not vary significantly. The safety and effectiveness of the Verres Needle and Cannula are comparable to that of the Gynescope Trocar and Sleeves and the Marlow Verres Needle.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 1997

Ms. Debra A. Pekar
Manager of Quality Assurance and Regulatory Affairs
CooperSurgical, Inc.
15 Forest Parkway
Shelton, Connecticut 06484

Re: K971837
VerreScope Verres Needle and Cannula
Dated: May 16, 1997
Received: May 19, 1997
Regulatory class: II
21 CFR §884.1720/Product code: 85 HET

Dear Ms. Pekar

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) 594-4613. 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,

Lillian Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K971837

Device Name: Verres Needle / Cannula

Indications For Use:

Verres Needle and Cannula is intended for use in laparoscopic surgery that utilizes minimally invasive surgical procedures to establish pneumoperitoneum and to provide access for operative and diagnostic instrumentation.

CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Colin M Pollard

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K971837

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)