K000422

MAR 3 1 2000

Exhibit 9.

510(k) Summary

SOPRO feels the S-57D Camera is substantially equivalent to the many marketed devices already in commercial distribution. The legally marketed devices already in commercial distribution are : Olympus and Storz just to name a few.

The design of the S-57D is virtually identical to the comparative devices, which are listed and displayed in Exhibit 2 and 3. Since the design is comparable, technology virtually identical, the specifications very similar, and the intended use the sames, SOPRO feels that these minors differences have no impact on the safe use and/or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 1 2000

Mr. Pierre Montillot
Chief Executive Officer
SOPRO
Place St. Christophe
Les Accates-La Valentine
13011 Marseille,
France

Re: K000422
Trade Name: S57D Digital Operating Room Camera
Regulatory Class: II
Product Code: GCJ
Dated: February 4, 2000
Received: February 9, 2000

Dear Mr. Montillot:

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,

for 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

510(k) NUMBER (IF KNOWN): K000422

DEVICE NAME: SSTD Digital Operating Room Camera

INDICATIONS FOR USE:

Provide access, illumination and allow observation of manipulation of body cavities hollow organs and canals

FDA/CDRH/ODE/DMC
28 FEB 00 10 07
RECEIVED

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000422