Exhibit 9.

K973796

JAN - 2 1998

510(k) Summary

SOPRO feels the S 41 & S 41 S Video Imaging Systems are substantially equivalent to the many marketed devices already in commercial distribution. The legally marketed devices already in commercial distribution are : Circon/ACMI, Storz, Stryker, Smith & Nephew and Olympus, just to name a few.

The design of the S 41 & S41S 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.

For information purposes and completeness, SOPRO has also incorporated other legally marketed devices in this filling to illustrate the wide general use of similar other devices. This wide use had led us to the safe use of this device in many practitioner's hands.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 2 1998

Mr. Pierre Montillot
C.E.O.
SOPRO
Place St. Christophe
Les Accates-La Valentine
Marseille,
FRANCE

Re: K973796
Trade Name: S-41 & 41S Video Imaging System
Regulatory Class: II
Product Code: GCJ
Dated: October 2, 1997
Received: October 6, 1997

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 requirements , 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

10(k) Number (if known):_____

Device Name: 30RG41 & 41S

Indications For Use:

Assist in the observation and recording of surgical procedures performed in body cavities, hollow organs and canals

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use___

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973796