

MAR 13 2000

510(k) SUMMARY

Soprane S.A. Fertiloscopy Kit® FH 1.29 / FTO 1.40

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared:

August 6, 1999

Name of Device and Name/Address of Sponsor

Soprane S.A, Fertiloscopy Kit® FH 1.29 / FTO 1.40

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Common or Usual Name

Intrauterine Balloon Catheter and Transvaginal Cannula

Classification Name

Rigid culdoscope and accessories (21 C.F.R. § 884.1640); semi-rigid hysteroscope and accessories (21 C.F.R. § 884.1690); cannula, manipulator/injector, uterine; and reposable surgical trocar (21 C.F.R. § 884.1720)

Predicate Devices

- Circon Corporation's ("Circon") Transvaginal Hydro® Laparoscopy ("THL™") System;

- Cook OB/GYN's ("Cook") Intrauterine Balloon Access Catheter ("IBA Catheter");
- Imagyn Medical, Inc.'s ("Imagyn") MicroSpan Hysteroscope Sheath ("MicroSpan"); and
- Origin Medsystems, Inc.'s ("Origin") Blunt Tip Trocar.

Intended Use

The Fertiloscopy Kit is intended to be used for transvaginal hydro-laparoscopy, dye-test, salpingoscopy, and hysteroscopy during one procedure. The device is indicated for use in the diagnosis of tubo-peritoneal infertility.

Technological Characteristics and Substantial Equivalence

The Fertiloscopy Kit has the same general intended use and similar principles of operation and technological characteristics as a combination of Circon's cleared THL, Cook's cleared IBA Catheter, Imagyn's cleared MicroSpan, and Origin's cleared Blunt Tip Trocar. The minor technological differences between the Fertiloscopy Kit and the Imagyn MicroSpan, Cook IBA Catheter, Circon THL, and Origin Blunt Tip Trocar do not raise any new questions of safety or effectiveness. Therefore, the Fertiloscopy Kit is substantially equivalent to its predicate devices.

Performance Data

Soprane has conducted leak testing of the balloon during inflation and sterility testing of the materials following sterilization. In a clinical study of 160 patients, Fertiloscopy was shown to provide a "diagnostic sequence giving, in a one time procedure, a complete and informative status of the uterus, tubes, ovary, and peritoneum."

Conclusion

The Fertiloscopy Kit's substantial equivalence is based on a narrative comparison of this device and its predicate devices' intended use, principles of operation and technological characteristics and bench testing and clinical testing.



MAR 13 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Soprane S.A.
c/o Mr. Howard M. Holstein
Hogan & Hartson, L.L.P.
555 Thirteenth Street, N.W.
Washington, D.C. 20004Re: K992655
Fertiloscopy Kit ® FH 1.29/FTO 1.40
Dated: January 18, 2000
Received: January 19, 2000
Regulatory Class: II
21 CFR §884.1640/Procode: 85 HEW
21 CFR §884.1690/Procode: 85 HIH
21 CFR §884.1720/Procode: 85 HET

Dear Mr. Holstein:

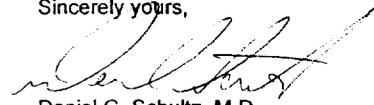
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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) 594-4591. 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" (21CFR 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/dsma/dsmamain.html>".

Sincerely yours,



Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K992655

Device Name: Soprane S.A.'s Fertiloscopy Kit® FH 1.29 / FTO 1.40

Indications for Use:

The Fertiloscopy Kit is intended to be used for transvaginal hydro-laparoscopy, dye-test, salpingoscopy, and hysteroscopy during one procedure. The device is indicated for use in the diagnosis of tubo-peritoneal infertility.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 C.F.R. 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992655