K023930

510 (k) Summary

JAN 22 2003

Date Prepared [21 CFR 807.92(a)(1)]

November 22, 2002

Submitter's Information [21 CFR 807.92(a)(1)]

Joseph M. Azary
C/o CooperSurgical Inc.
543 Long Hill Avenue
Shelton, CT. 06484

Azary Technologies has received authorization to submit this 510(k) on behalf of the sponsor CooperSurgical Inc., 95 Corporate Drive, Trumbull, CT 06611.

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

The device trade names are: CooperSurgical Oocyte Recovery Needles

Common Name: Assisted Reproduction Needles

Predicate Device [21 CFR 807.92(a)(3)]

SIMS Portex, Wallace Oocyte Retrieval Set – K012068

The subject devices have the same indications for use, material composition, sterilization method, and working dimensions. The main difference is the luer of the subject device is slightly larger (both in diameter and length) than the predicate device and the subject device has a needle hub composed of ABS instead of methyl pentene.

Description of the Device [21 CFR 807.92(a)(4)]

The oocyte recovery needles are single use sterile devices provided for ultrasound guided transvaginal collection and recovery of oocytes from ovarian follicles for use during assisted conception procedures. The set consist of a single lumen, stainless steel needle attached to tubing. The needle is 33 cm in length and available in 16 Ga. or 17 Ga. Each device has 2 cm of echogenic markings at the distal tip for ultrasound reflection and a plastic hub at the proximal end for ease of guidance by hand. The tubing is attached to the proximal end of the needle and protrudes a total distance of 90 cm until it terminates in a silicone bung.

The subject devices will be packaged in a flexible pouch composed of Tyvek heat sealed to polyethylene film. The pouch is designed to be peeled open. The pouch will be placed in a white carton box. Each carton will contain 10 units. The subject devices will be sterilized using Ethylene Oxide using SAL 10^{-6}.

The two versions to be offered are: 16 Ga. (AR-N1695) and 17 Ga. (AR-N1795).

The subject devices are composed of the following materials:

Component	Material	Details
Needle Hub	ABS (Acrylonitrile Butadiene Styrene)	Bayer Lustran 266 ABS
Needle	Stainless Steel	304 Stainless Steel
Needle Guard	Polyethylene	No patient contact
Stopper	Silicone	Dow Corning Material Q7-4840
Luer	Polypropylene	Montellprofax 6323 Compounded by Chroma with PMS 240 U Pink.
Large OD Tubing	Polyurethane	Pellethane 2363-90A R0120 Polyurethane
Small OD Tubing	Polyurethane	Pellethane 2363-90A R0120 Polyurethane
Small Sleeve	Silicone	Dow Corning Material Q7-4840
Tip Protector	Polyethylene	No patient contact

Intended Use [21 CFR 807.92(a)(5)]

The device is for ultrasound guided transvaginal recovery and collection of oocytes from ovarian follicles.

Technological Characteristics [21 CFR 807.92(a)(6)]

CooperSurgical Inc. believes that the subject device is substantially equivalent to the predicate device. The subject device is composed of the same materials, sterilized using the same method, complies with the same standards, has the same indications for use, and is similar dimensionally. There are minor differences with the packaging, outer diameter and length of the Luer, and the material of the needle hub.

Performance Data [21 CFR 807.92(b)(1)]

The subject device has been subject to biocompatibility testing (for the materials that contact the patient) that is equivalent to ISO 10993-1 Biocompatibility requirements. The subject device also complies with ISO 594-1 1986 Conical fittings with a 6% (luer) taper requirements.

Conclusion [21 CFR 807.92(b)(3)]

We believe the changes are minor and conclude that the subject devices are as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 22 2003

CooperSurgical, Inc.
% Mr. Joseph M. Azary
Manager
AZARY Technologies, LLC
P.O. Box 2156
HUNTINGTON CT 06484

Re: K023930
Trade/Device Name: CooperSurgical Oocyte Recovery Needles
Regulation Number: 21 CFR 884.6100
Regulation Name: Assisted reproduction needles
Regulatory Class: II
Product Code: 85 MQE
Dated: November 22, 2002
Received: November 25, 2002

Dear Mr. Azary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

5 10(k) Number (if known): K023930

Device Name: CooperSurgical Inc. Oocyte Recovery Needles

Indications For Use: The device is for ultrasound guided transvaginal recovery and collection of oocytes from ovarian follicles.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

David A. Clymer

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023930

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

(Optional Format 1-2-96)