K023384

510 (k) Summary

DEC 13 2002

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

October 7, 2002

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

Joseph M. Azary
C/o CooperSurgical, Inc.
P.O. Box 2156
Huntington, 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. CooperSurgical, Inc. is an FDA-registered medical device under establishment# 1216677.

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

Trade names are: CooperSurgical Trial Transfer Catheter

Common Name: Assisted Reproduction Catheter

Classification: Class II, 21 CFR 884.6110, MQF

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

- Wallace Trial Transfer Catheter – K990348

The subject devices have the same indications for use, material composition, sterilization method, and working dimensions as the predicate. A minor difference lies in the fact that the luers of the subject device are slightly larger (both in diameter and length) than the predicate device. The subject device is packaged in a pouch composed of Tyvek and film, whereas the predicate device is packaged in a pouch composed of paper and film. Additional information regarding the predicate device can be found in Annex 4. A chart comparing the subject device to the predicate device can be found in Annex 7.

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

The CooperSurgical Trial Transfer catheters are single-use sterile, disposable, flexible catheters with a round smooth distal end. The tip has a blind/closed end. The device has an overall length of either 18cm or 23cm including a polypropylene Luer Lock Adaptor that is affixed at its proximal end. The inner catheter is a clear tube with a 1.8mm outer diameter and a 0.8mm inner diameter. The inner catheter is surrounded by an outer sheath with a 2.3mm outer diameter. This inner catheter has a series of graduated markings that are placed 1cm apart at the proximal end to provide reference to the degree of inner catheter insertion to the uterus during embryo placement. The distal 0.1cm length of the outer sheath possesses a gradual taper and is shorter than the inner catheter leaving the distal 5cm of the inner catheter exposed. The proximal circumferences of the outer sheath and inner catheter are molded directly into the distal end of the Luer Lock Adaptor. Five black (ink) graduation markings are located on the distal portion of the outer sheath at 1cm increments to indicate the degree of advanced into the cervix. This facilitates catheter positioning and placement during embryo replacement with an assisted reproduction catheter.

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 pouches will be placed in a carton. Each carton will contain 10 units.

The two versions to be offered are: AR-TT18 (18cm) and AR-TT23 (23cm).

The subject devices are composed of the following materials:

Component	Material	Details
Inner Catheter	Polyurethane	Pellethane 2363-90A R0120 Polyurethane
Outer Sheath	Teflon	Fluortek FEP-20 White (aka Neoflon NP-20) with 8-10% Barium Sulfate.
Luers	Polypropylene (with colorants).	Montell Profax 6323 Compounded by Chroma with PMS 240 U Pink. Montell Profax 6323 Natural compounded by Chroma with FDA white colorant.
Tip Protector	Polyethylene	No patient contact

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

The sterile single-use device is intended to assess advancement through the cervical canal and positioning of the uterus.

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. The only differences are with the packaging and the outer diameter and length of the Luer.

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

DEC 13 2002

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

Re: K023384
Trade/Device Name: CooperSurgical, Inc.
Trial Transfer Catheter
Regulation Number: 21 CFR 884.6110
Regulation Name: Assisted reproduction
catheters
Regulatory Class: II
Product Code: 85 MQF
Dated: December 3, 2002
Received: December 4, 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 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 this 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" (21 CFR Part 807.97). 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): K023384

Device Name: CooperSurgical, Inc. Trial Transfer Catheter

The sterile single-use device is intended to assess advancement through the cervical canal and positioning of the uterus.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023384

Prescription Use V
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)