DEC 2 0 2002

K023382

510 (k) Summary

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.

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

Possible device trade names are: CooperSurgical Malleable Stylet or Edwards Malleable Stylet

Common Name: Assisted Reproduction Catheters, Stylet

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

Wallace Malleable Stylets - K990349

The subject devices have the same indications for use, material composition, sterilization method, and working dimensions as the predicate device. 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.

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

Assisted Reproduction Catheters / Stylets are single-use sterile devices provided for use with CooperSurgical Assisted Reproduction Catheters, should passage through the cervix be impeded. The devices have an overall length of 23cm and 18cm and consist of a malleable inner stylet and a detachable rigid outer sheath, which is attached to the flexible inner stylet by a male/female Luer Lock adaptor. When the outer sheath Luer is attached to the hub of the stylet, the inner malleable stylet forms a smooth radius at the tip of the outer sheath. The outer sheath has a series of 1cm graduations at the distal end. The stainless steel stylet is encapsulated in Teflon (FEP).

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 are AR-ST18 (18cm length) and AR-ST23 (23cm length).

The subject devices are composed of the following materials:

Component	Material	Details
Stylet Outer Sheath	Teflon	Fluortek FEP-20 White (aka Neoflon NP-20)
Stylet Inner Rod	Stainless Steel	No patient contact. The 316 Stainless Steel is encapsulated in Teflon (FEP).
Outer Sheath	Teflon	Fluortek FEP-20 White (aka Neoflon NP-20)
Luers	Polypropylene (pink colorant used in outer luer and blue colorant used in stylet luer).	Montell Profax 6323 Compounded by Chroma with PMS 240 U Pink. Montell Profax 6323 Compounded by Chroma with PMS 300C Blue.
Tip Protector	Polyethylene	No patient contact

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

The sterile singe-use devices are to be used in conjunction with an Edwards Catheter for in-vitro fertilization procedures where passage through the cervix is impeded.

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 has the same working dimensions. The minor 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 2 0 2002

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

Re: K023382
Trade/Device Name: CooperSurgical, Inc. Malleable Stylet
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): K023382

Device Name: CooperSurgical, Inc. Malleable Stylet

Indications For Use: The sterile singe-use devices are to be used in conjunction with CooperSurgical Assisted Reproduction Catheters for in-vitro fertilization procedures where passage through the cervix is impeded.

(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)

David G. Hyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023382