AUG - 9 2004

K041562

510(k) SUMMARY AS REQUIRED BY SECTION 807.92(c)

Submitted by: Irvine Scientific Sales Co., Inc.
2511 Daimler Street
Santa Ana, CA 92705-5588

Telephone: (800) 437-5706
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Contact: Wendell Lee, Pharm. D.

Date Submitted: June 9, 2004

Device Identification:

Trade Name:	CryoTip
Common Name:	Cryopreservation container and microtool
Classification Name:	Assisted Reproduction Microtools (21 CFR, 884.6130)

Predicate Device:

Notice of Final Rule, 63 FR 48428, Docket number 97N-0335

Description:

The CryoTip is a medical grade plastic drawn device designed to contain, freeze and maintain oocytes and/or embryos. It has a fine tip at one end (drawn to an inner diameter of ~200 micrometers), along with a stainless steel cover sleeve which can slide along the length of the CryoTip to expose or cover and protect the fine drawn tip. This device is designed to be heat sealed on each end of the plastic straw to create a closed system for long-term frozen storage of oocytes and/or embryos. The CryoTip has four (4) identifiable marks at specified locations to aid the Embryologist in loading the specimens into the optimal regions of the device during Cryo Preservation procedures.

The device is designed to be heat sealed using an impulse heat sealer after the oocytes and/or embryos have been drawn into the fine tip. The fine tip

end of the CryoTip is heat sealed first. The Embryologist aseptically places the fine tip of the CryoTip onto the bottom base of the heat sealer just below the first marking on the CryoTip. The pressure lever is then lowered onto the fine tip of the CryoTip for sealing. When the heat sealing process is complete the pressure lever is lifted and the CryoTip is removed. The Embryologist will then carefully slide the metal cover sleeve over the heat sealed fine tip. After the fine tip of the CryoTip is sealed the connector is aseptically removed from the CryoTip. The open end of the CryoTip is then placed onto the center of the bottom base of the heat sealer just above the fourth marking. The pressure level is lowered onto the CryoTip for sealing. When the heat sealing process is complete the pressure lever is lifted from the CryoTip and the CryoTip is removed from the heat sealer. After both ends of the CryoTip have been sealed the Embryologist places the sealed CryoTip into a liquid nitrogen reservoir for storage.

Intended Use:

The CryoTip is a cryopreservation device that is intended to be used to contain, freeze and maintain oocytes and/or embryos.

Performance Data:

The CryoTip device has been studied by five (5) independent field laboratories, using one-cell mouse embryos and the protocol for mouse embryo assay. The response and feedback from the laboratories that evaluated the device indicates it was well received in terms of its application, ease of use, and effectiveness in the cryopreservation procedures.

Additional Information:

Mouse Embryo Assays and sterility tests will be performed as a condition of release for these products, as appropriate. Results of all release assays performed will be reported on a lot-specific certificate of analysis, and will be indicated on the labeling. Please refer to the proposed certificate of analysis and

presented in Appendix C and the proposed labeling presented in section 14 of this submission.

Conclusion:

The results from the field testing of these products demonstrates that CryoTips are suitable for their intended use, and meet the criteria outlined in the Notice of Final Rule, 63 FR 48428, Docket number 97N-0335.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 9 2004

Wendell Lee, Pharm. D.
Vice President, Quality Systems
and Regulatory Affairs
Irvine Scientific Co., Inc.
2511 Daimler Street
SANTA ANA CA 92705-5588

Re: K041562
Trade/Device Name: CryoTip, Cryopreservation container
Regulation Number: 21 CFR 884.6130
Regulation Name: Assisted reproduction microtools
Regulatory Class: II
Product Code: 85 MQH
Dated: June 9, 2004
Received: June 10, 2004

Dear Dr. Lee:

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 such 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

INDICATIONS FOR USE STATEMENT (page 1 of 1)

510(k) Number (if known): K041562

Device Name: CryoTip

Indications For Use:

The CryoTip is a cryopreservation device that is intended to be used to contain, freeze and maintain oocytes and/or embryos.

Prescription Use _X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 K041562