K050521

MAY - 2 2005

InnTec, Inc

Office-
401 E. Edgewater St.
Portage, WI. 53901
Phone 608-444-4544
Fax 608-846-6071

Shipping & Receiving-
121 Evco Circle
DeForest, WI. 53532

IUI Catheters

Oocyte Retrieval Needle Sets

Embryo Transfer Catheters

Custom Product Design & Manufacturing

Summary of Safety and Effectiveness

Company Name: InnTec, Inc.
401 E. Edgewater St.
Portage, WI 53901

Contact: Michael Kvalo, PE

Phone: 608 444-4544

Fax: 608 846-6071

Summary Date: February 24 ,2005

Trade Name: Embryo Transfer Catheter and Accessory Stylet

Common Name: Embryo Transfer Catheter

Classification Name: 21 CFR ; Product Code:

Predicate Device:

510(k)	Manufacturer	Product Code	Class	Trade Name
K992307	Life Tech Medical, Inc.	MQF	II	Embryo Glide™ Embryo Transfer Catheter and Accessory

1.0 Description of Device

The Embryo Transfer Catheter and Accessory Stylet are sterile, single patient use, disposable devices supporting transfer of an in vitro fertilized embryo to the uterus.

The Embryo Transfer Catheter is a 5 Fr Catheter within a 7 Fr Guide Sheath. The 5 Fr Catheter is in contact with the embryo and the uterus. The embryo passes through the Catheter, which is open at the end. The Catheter is available in 18 and 23 cm lengths. The Catheter has marks at 1 cm intervals for depth of insertion.

The 7 Fr Guide Sheath provides a smooth passage into the uterus and is open at the end. This Guide Sheath is available in 18 and 23 cm lengths. The Guide Sheath has marks at 1 cm intervals for depth of insertion. Both the 5 Fr Catheter and 7 Fr Guide Sheath have color-coded hubs to indicate the length variation.

An optional accessory stylet is available to aid in the initial placement of the Guide Sheath. Both 18 and 23 cm length stylets are available.

The assembly of Embryo Transfer Catheter and Guide Sheath are packaged in a commercially available, sterile barrier pouch. The Accessory Stylet is also placed in a commercially available, sterile barrier pouch.

2.0 Intended Use

The InnTec, Inc. Embryo Transfer Catheter and Accessory Stylet is an assisted reproduction catheter used in IVF assisted reproduction procedures to introduce embryo(s) into the female uterus.

3.0 Technology

The technology of the device is the same as the predicate.

4.0 Conclusions

The intended use, technology, materials and manufacturing processes of the InnTec, Inc. Embryo Transfer Catheter and Accessory Stylet are the same as the predicate device. No new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2005

InnTec, Inc.
% Mr. Gary Syring
Principal Consultant
Quality & Regulatory Associates, LLC
800 Levanger Lane
STOUGHTON WI 53589

Re: K050521
Trade/Device Name: Embryo Transfer Catheter and Accessory Stylet
Regulatory Number: 21 CFR 884.6110
Regulation Name: Assisted reproduction catheters
Regulatory Class: II
Product Code: MQF
Dated: April 18, 2005
Received: April 19, 2005

Dear Mr. Syring:

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 (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 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.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

510(k) Number (if known): K050521

Device Name: Embryo Transfer Catheter and Accessory Stylet

Indications for Use:

The InnTec, Inc. Embryo Transfer Catheter and Accessory Stylet is an assisted reproduction catheter used in IVF assisted reproduction procedures to introduce embryo(s) into the female uterus.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 K050521