NOV 2 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

510(k) Summary

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: October 10, 2005

Trade Name: IUI Catheter

Common Name: Assisted Reproduction Catheter

Classification Name: 21 CFR 884.6110; Product Code: MQF

Predicate Device:

510(k)	Manufacturer	Product Code	Class	Trade Name
K921518	Lifetek Medical, Inc.	MFD	II	IUI Catheter

1.0 Description of Device

The InnTec IUI Catheter has been specifically designed for Intrauterine Inseminations. The over all Catheter length is 17.5cm, and tapers from 7 Fr. at the hub down to 5 Fr at the distal tip which is 5cm long. The tip is closed and smoothly rounded, eyelets are located at 180° from one another. Catheter internal volume is .07cc. Centimeter marks are printed at 6, 7, 8, 9, & 10cm from the tip, the ink is non-toxic and will not rub off.

2.0 Intended Use

The InnTec, Inc. Intrauterine Insemination (IUI) Catheter is used for intrauterine insemination.

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. IUI Catheter are the same as the predicate device. No new questions of safety or effectiveness are raised.

Standards Data Form for Abbreviated 510(k)s

510(k) Number:	K052059 InnTec, Inc. - IUI Catheter
Standard Organization No:	ANSI/AAMI/ISO
Standard Identification No:	10993 Part 7
CDRH Internal Reference No:	10

Declaration of Conformity Elements:				
Any Adaptations Applied	yes		no	X
Any Requirements Not Applicable	yes		no	X
Any Deviations Applied	yes	X	no	
Any Differences in Device Tested and Finished Product	yes		no	X
*Is There a Third Party or Test Lab Involved	yes	X	no	

Was there another standard used in the review of this submission? yes X no

If another standard was used, please fill out an additional form.

* This is not the third party that reviews 510ks

Standards Data Form for Abbreviated 510(k)s

510(k) Number:	K052059 InnTec, Inc. - IUI Catheter
Standard Organization No:	ANSI/AAMI/ISO
Standard Identification No:	11135
CDRH Internal Reference No:	7

Declaration of Conformity Elements:				
Any Adaptations Applied	yes		no	X
Any Requirements Not Applicable	yes	X	no	
Any Deviations Applied	yes		no	X
Any Differences in Device Tested and Finished Product	yes		no	X
*Is There a Third Party or Test Lab Involved	yes	X	no	

Was there another standard used in the review of this submission? yes X no

If another standard was used, please fill out an additional form.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 2 2005

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

Re.: K052059
Trade/Device Name: IUI Catheter
Regulation Number: 21 CFR 884.6110
Regulation Name: Assisted reproduction catheters
Regulatory Class: II
Product Code: MQF
Dated: October 24, 2005
Received: October 31, 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 (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 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

Indications for Use

510(k) Number (if known): K052059

Device Name: IUI Catheter

Indications for Use:

The InnTec, Inc. Intrauterine Insemination (IUI) Catheter is used for intrauterine insemination.

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)

David G. Jogerson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052059