### 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:**

<table>
<thead>
<tr>
<th>510(k) Manufacture Code</th>
<th>Product Code</th>
<th>Class</th>
<th>Trade Name</th>
</tr>
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<tbody>
<tr>
<td>K921518</td>
<td>Lifetek Medical, Inc.</td>
<td>MFD</td>
<td>IUI Catheter</td>
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</table>

#### 1.0 Description of Device

The InnTec IUI Catheter has been specifically designed for Intrauterine Inseminations. The overall 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.

* This is not the third party that reviews 510ks
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
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 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)