K021438
Page 1 of 2

Labotect Insemination Catheter 320301: abbreviated 510(k)submission

JUL 16 2002

Summary of Safety and Effectiveness

Submitted By:

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37079 Göttingen
Germany
Telephone number: 01149 551 505010
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Date 2002-05-01

Device:

Trade Name:	Insemination Catheter
Proposed Classification Name:	Assisted Reproduction Catheters Class II 85 MQF

Predicate Devices:
Edwards-Wallace Bourne-Hall (k910577)
Marlow-Surgical

Embryon Intra-uterine Insemination Catheters (k980061)
Rocket Medical

Mini-Embryon Intra Uterine Insemination Catheter (k972823)
A&A Medical, Inc.

MedWorks Insemination Catheter (k982628)
MedWorks Corp.

Jansen-Anderson Insemination Set (k914150)
Cook OB/Gyn

Device description and intended use:
The Insemination Catheters are used for transferring sperms into the uterine cavity. They have a well rounded tip and two distal side ports. The insemination fluid is introduced using a syringe attached to the proximal luer. The material used in these devices is Polypropylene. Biocompatibility is assured according to ISO 10993.

Special Controls:
These insemination catheters are manufactured and marketed according to special controls of 21CFR Sec. 884.6110.

- Mouse Embryo Assay batch tested: Two-Cell-MEA, blastocyst hatching >80%
- Endotoxin batch tested: Bacterial Endotoxin Assay, Endotoxin Value < 0,25 EU/ml
- Sterilization Validation: Gamma sterilization validated according to ANSI/AAMI/ISO 11137 and EN 556, SAL 10^{-6}
- Design specifications were made to meet the requirements for insemination catheters
- The Labelling meets the requirements of 21 CFR Part 801 and Part 884, special controls
- Biocompatibility was tested according to Blue Book memorandum #G95-1 entitled " Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing." The devices are tested on cytotoxicity, sensitization and irritation or intracoutaneous reactivity using GLP methods.
- Clinical application is evaluated using a "Post-Marketing-Surveillance-System" to collect and analyse data from clinical application. These Insemination Catheters are marketed for more than 10 years in the EU without any adverse events.

Substantial Equivalence:
The Insemination Catheters are substantially equivalent to the predicate devices with respect to the indications for use, design and performance specifications.

Conclusion:
Based on indications for use, technological characteristics, and comparison to currently marketed insemination catheters, the Labotect-Insemination Catheter has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2002

Ms. Angelika Albrecht
Quality Manager
Labotect GmbH
Labor-Technik-Göttingen
Willi-Eichler-StraBe 25
D-37079 Göttingen
GERMANY

Re: K021438
Trade/Device Name: Insemination Catheter, Model 320301
Regulation Number: None
Regulatory Class: Unclassified
Product Code: 85 MFD
Dated: June 19, 2002
Received: July 5, 2002

Dear Ms. Albrecht:

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

510(k) Number (if known): K021438

Device Name: Insemination Catheter

Indications For Use:

The catheter is used for intrauterine insemination.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

David G. Lagerman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021438

(Optional Format 1-2-96)