AUG 2 7 2001

K012220
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Chapter 5 TRADITIONAL 510(K) SUMMARY
Tao Embryo Transfer Catheter System

APPLICATION DATE:	May 22, 2001
APPLICANT:	TTJ Biomedical, LLC 2885 Aurora Avenue, Suite 15 Boulder, CO 80303 303-444-5026 303-444-9713 (fax)
CONTACT:	Richard Jortberg, MS, MAI Manager, TTJ Biomedical, LLC 2885 Aurora Avenue, Suite 15 Boulder, CO 80303 303-444-5026; 303-444-9713 (fax) REJ@RJAssociatesInc.Com
TRADE NAME:	Tao Embryo Transfer Catheter System
COMMON NAME:	Embryo Transfer Catheter
CLASSIFICATION NAME:	Assisted Reproduction Catheter
DEVICE CLASS:	Class II
REGISTRATION NUMBER:	To be registered upon completion of 510(K) review process
REGULATION NUMBER:	21 CFR 884.6110
PRODUCT CODE (PROCODE):	85 MQF
510(K) TYPE:	Traditional

TRADITIONAL 510(K) SUMMARY (Continued)
Tao Embryo Transfer Catheter System

SUBSTANTIAL EQUIVALENCE / PREDICATE DEVICES:

The Tao Embryo Transfer Catheter system is substantially equivalent to applicable published requirements due to conformance with descriptions from CFR 884.6110 Assisted Reproduction Catheters as described in the Final Rule in the Federal Register, Vol. 63, No. 175, September 10, 1998, page 48436. In addition, the Tao catheter is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or devices that have been reclassified in accordance with the provisions of the Federal Food, Drug and Cosmetic Act. Finally, due to similarity with respect to indications for use, materials and physical construction to predicate devices, the Tao catheter meets the requirement for section 510(K) substantial equivalence.

INDICATIONS FOR USE:

Devices are intended for single use, limited exposure (<24 hours), mucosal membrane surface contact, embryo transfer procedures. The sterile Tao Embryo Transfer Catheter system is intended for use for the introduction of embryos into the uterine cavity. The procedure should be completed by an individual with requisite experience and education in the process of IVF and embryo transfers, and the procedure should be completed in a facility suited for IVF and embryo transfers. The catheter system consists of a single use, ETO sterilized inner catheter and outer sleeve.

DEVICE DESCRIPTION/ TECHNICAL CHARACTERISTICS:

The Tao Embryo Transfer Catheter system consists of two devices which are used for introducing embryos into the uterine cavity. This sterile, single use embryo transfer system consists of a pellethane outer sleeve and a polyethelene inner catheter. The outer sleeve has a distal portion which has an easy-to-shape design. At the tip, the outer sleeve is protected by a sphere-shaped soft cap. The revolutionary design of the cap not only significantly minimizes trauma when passing the cervix, but it also minimizes possible mucus, blood and bacterial contamination of the inner catheter and embryos. The inner catheter has two different designs, with one having an end-port and the other a side-port. Predicate devices do not use the proprietary design of the sphere-shaped cap of the outer sleeve.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 7 2001

Mr. Richard Jortberg, MS, MAI
Manager, TTJ Biomedical, LLC
TTJ Biomedical, LLC
2885 Aurora Avenue, Suite 15
BOULDER CO 80303

Re: K012220
Tao Embryo Transfer Catheter System
(IVF Reproduction Transfer Catheter)
Dated: May 22, 2001
Received: July 16, 2001
Regulatory Class: II
21 CFR 884.6110/Procode: 85 MQF

Dear Mr. Jortberg:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. 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 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

Chapter 4 STATEMENT OF INDICATIONS FOR USE:

Ver/ 3 - 4/24/96
Applicant: TTJ Biomedical, LLC
510(k) Number (if known): K012220
Device Name: Tao Embryo Transfer Catheter System
Indications For Use:

Intended Use: Single use, limited exposure (<24 hours), mucosal membrane surface contact, embryo transfer procedures. The Tao embryo transfer catheter system is intended for use for the introduction of embryos into the uterine cavity. The procedure should be completed by an individual with requisite experience and education in the process of IVF and embryo transfers, and the procedure should be completed in a facility suited for IVF and embryo transfers. The catheter system consists of a single use, ETO sterilized inner catheter and outer sleeve.

Prescription Use ✓

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012220