P1072

K974028

ATTACHMENT C

Conceptus

JAN 21 1998

510(K) SUMMARY

As required by 21 CFR section 807.92(c)

Submitter's Name, Address, Phone and Fax Number

Conceptus, Inc.
1021 Howard Ave.
San Carlos, CA 94070
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Contact Person

Connie Acuff
Manager
Regulatory Affairs & Clinical Research

Date Summary Prepared

October 21, 1997

Device Names

Trade Name:	Stargate™ Falloposcopy Catheter and Trifurcated Irrigation Tubing Set (part of STARRT™ Falloposcopy System)
Common Name:	falloposcopy catheter and irrigation tubing
Classification Name:	Uterotubal carbon dioxide insufflator and accessories (per 21 CFR 884.1300)

Device to Which Substantial Equivalence was Claimed

Substantial Equivalence for the Stargate Falloposcopy Catheter was claimed to the Conceptus VS™ Catheter which, as part of the STARRT Falloposcopy System, was previously cleared for the diagnosis of Proximal Tubal Occlusion (PTO). Substantial Equivalence for the Trifurcated Irrigation Tubing was claimed to the Clarus Medical, Model 5150 Tubing Set which was previously cleared for fluid infusion for clearing the field of vision with endoscopes.

Device Description

The Conceptus Stargate Catheter is a single lumen device with a graded shaft flexibility. The distal end has a diamond shaped wire tip designed to guide the catheter and to keep fallopian tube epithelium away from the falloposcope lens during imaging. The hub located at the proximal end of the Conceptus Stargate Catheter has two ports. The sideport is used for the attachment of the Trifurcated Irrigation Tubing set. The endport serves as a conduit for the introduction of the Conceptus Falloposcopy Guidewire and Falloposcope.

K974026

P292

Device Description, cont.

The Conceptus Stargate Catheter and Falloposcopy Guidewire are transcervically delivered into the fallopian tube ostium through the lumen of the Coaxess™ Catheter which is delivered into the uterine cavity through the working channel of a rigid hysteroscope and positioned at the tubal ostium under hysteroscopic guidance. The Conceptus Stargate Catheter and Falloposcopy Guidewire are designed for use within the proximal portion of the fallopian tube (the first 2-3 cm of the tube).

Intended Use

The Stargate Catheter as part of the STARRT Falloposcopy System is intended for use as a secondary diagnostic tool for further evaluation of women previously diagnosed with proximal tubal occlusion by hysterosalpingography or selective salpingography.

Technological Characteristics

The Conceptus Stargate Catheter is substantially equivalent to the Conceptus VS Catheter and will replace that device in the Conceptus STARRT Falloposcopy System. The primary difference between the Stargate Catheter and VS Catheter is a diamond shaped wire which has been added to the distal tip of the Stargate Catheter. The primary purpose of the wire tip is to keep tubal epithelium away from the falloposcope lens to optimize imaging of the fallopian tube lumen.

Data Supporting Substantial Equivalence

Conceptus conducted laboratory, preclinical and clinical testing to confirm that the Stargate Catheter is safe and effective. The laboratory testing demonstrated that small forces are applied to the wire tip during clinical use. Laboratory testing further demonstrated that the force required to advance the Stargate Catheter is no greater than the force required to advance the VS Catheter. Lastly, laboratory testing confirmed that the Stargate Catheter is less likely to kink as compared to the VS Catheter.

A fallopian tube catheterization histology study in rabbits was conducted to demonstrate the safety of the Stargate Catheter. The objective of the study was to use the rabbit model to determine if fallopian tube catheterization as well as anticipated adverse events cause damage to the fallopian tube and if there is any resulting adverse impact on pregnancy rates. Study results demonstrate that their is no significant difference in fallopian tube damage between the catheterized and control tubes.

Lastly, clinical testing was conducted to validate the performance of the device. Participating clinicians reported that they were able to make a better diagnosis of tubal health with the Stargate Catheter as compared to the VS Catheter.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 21 1998

Ms. Connie Acuff
Manager, Clinical Research & Regulatory Affairs
Conceptus, Inc.
1021 Howard Avenue
San Carlos, CA 94070

Re: K974028
Stargate™ Falloposcopy Catheter and
Trifurcated Irrigation Tubing
Dated: October 21, 1997
Received: October 23, 1997
Regulatory Class: II
21 CFR 884.1690/Procode: 85 MKO

Dear Ms. Acuff:

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 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 requirement, 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) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K974028

Device Name: Stargate™ Falloposcopy Catheter and Trifurcated Irrigation Tubing Set (part of STARRT™ Falloposcopy System)

Indications for Use:

The STARRT System is indicated for use as a secondary diagnostic tool for the further evaluation of women previously diagnosed with proximal tubal occlusion by hysterosalpingography or selective salpingography.

- The STARRT System is only designed to access the *proximal* portion of the fallopian tube, i.e. the first 2-3 cm. It should only be advanced as far as necessary to achieve a meaningful study, recognizing that possible adverse effects of more distal advancement, particularly upon normal tubes, have not yet been determined.
- The STARRT System is not intended for tubal recanalization, and there is no data available, in particular, pregnancy data, showing clinical benefit for this use. Studies are underway.
- The STARRT System is not to be used for gamete or embryo transfer, or other assisted reproduction techniques.
- The STARRT System should only be used by clinicians with experience in tubal evaluation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D. Watkins

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K974028

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)