K063227

SECTION 5 - 510(K) SUMMARY

Submitter: Conceivex, Inc.
5 East Main Street
Saranac, MI 48881
616-642-0257

MAR 14 2007

Contact: Michael LaVean

Date of Summary: October 15, 2006

Common Name: Convenience Kit for Assisted Reproduction
Trade Name: Conceivex Conception Kit
Classification Name: Unclassified

A. Predicate Devices

Two of the 510(k)-cleared devices in the Conceivex Conception Kit are being submitted in this Premarket Notification, each with a new Indication for Use. The first predicate is the Oves Cervical Cap, K993953. The second is the Durex Avanti Polyurethane Condom, K902936.

B. Device Description

The Conceivex Conception Kit includes the following literature: Instructions for Use, a "Conception Wheel" to help plan in timing a pregnancy, a "Conception Journal" booklet to assist in charting the fertility cycle and keep track of medical information, and a Medical Provider Note to alert the woman's health care provider that she is trying to become pregnant.

The kit contains three identical boxes, each of which contain: one Oves Cervical Cap, one cervical cap for practice, one Avanti Semen Collection Condom, eight Ovulation Predictors, a Pregnancy Test, and a sample of 'Pre Vaginal Lubricant. The three boxes enable the woman to try to conceive by using the Kit through three ovulation cycles.

Once the couple has visited with a physician and decides they would like to become pregnant, they begin recording details of their cycle in the Conception Journal. Next, using the ovulation predictor, they identify their most fertile day in a given month. During sex they use the semen collector and afterwards transfer the specimen into the Conception Cap. The Conception Cap is then placed over the cervix for 4-6 hours. At the end of the woman's cycle, she uses the Conceivex pregnancy test kit to determine if conception has been achieved.

C. Intended Use

The Conceivex Conception Kit is indicated for assisted insemination in situations in which low sperm count, sperm immobility, or a hostile vaginal environment have been diagnosed. The kit is used for semen collection and placement into the bowl of a cervical cap as an aid to conception. It is to be used at home following physician instruction. The cap should not be left in place longer than 6 hours.

D. Substantial Equivalence Summary

The devices in the Kit are identical in all respects to the predicate devices. The Conceivex Conception Kit adds the following new indications for use to two of the components of the kit: Home Use to the Cervical Cap, and the Semen Collector to the Condom. Testing performed on both devices demonstrated that with the new Indications for Use, the devices are as safe and effective as the predicate devices and thus, are substantially equivalent to them.

The differences between the new indications for the devices that are the subject of this Premarket Notification, and the predicate devices, have been evaluated through testing to show that they are not critical to the intended theapeutic effect of the predicates, nor do they affect the safety or effectiveness of the devices when used as labeled.

E. Technological Characteristics

Because the two devices that are covered in this application are identical to the predicate devices, the technological characteristics of the new devices and the predicate devices are identical.

F. Testing

A Human Sperm Survival Assay and a Mouse Embryo Test performed on the non-latex condom demonstrated that the condom material has no deleterious effects on human semen or embryo development. Clinical testing carried out with the Cap demonstrated that the lay person can understand the revised Instructions for Use and manipulate and insert the cap correctly without direct supervision. The results of this testing demonstrate that the devices with the new Indications for Use are as safe and effective as their predicates.

G. Conclusion

This pre-market submission has demonstrated Substantial Equivalence as defined and understood in: Section 513(i) of the FD&C Act, as Amended; 21 CFR Section 807, and; guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAR 1 4 2007

Conceivex, Inc.
c/o Blix Winston, M.P.A., M.S.
Submission Correspondent
AC Consulting
2600 Mullinix Mill Road
MT AIRY MD 21771

Re: K063227
Trade/Device Name: Conceivex Conception Kit
Regulation Number: 21 CFR §884.5250
Regulation Name: Cervical cap
Regulatory Class: II
Product Code: OBB
Dated: February 22, 2007
Received: February 22, 2007

Dear Mr. Winston:

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 (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 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: K063227

Device Name: **Conceivex Conception Kit**

Indications for Use:

The Conceivex Conception Kit is indicated for assisted insemination in situations in which low sperm count, sperm immobility, or hostile vaginal environment have been diagnosed. The kit is used for semen collection and placement into the bowl of a cervical cap as an aid to conception. It is to be used at home following physician instruction. The Cap should not be left in place for longer than 6 hours.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063227