**TAB 2**

JUL 1 1 2014

# 510(K) SUMMARY – K140186 THE STORK® OTC

**Sponsor:** Rinovum Women's Health, Inc.
300 Oxford Drive
Suite 330
Monroeville, PA 15146

**Applicant:** Andrew Zeltwanger
Rinovum Women's Health, Inc.
300 Oxford Drive
Suite 330
Monroeville, PA 15146

**Phone:** 724-241-8934
**Facsimile:** 724-204-8141

**Date Prepared:** June 5, 2014

**Proprietary Name:** The Stork® OTC

**Common Name:** Conception Assistance Kit

**Classification Name:** Kit, Conception-Assist, Home Use (Product Code: OBB)

**Classification Panel:** Obstetrical/Gynecological

**Regulation:** 21 CFR § 884.5250, Cervical Cap

**Predicate Devices:**

| Manufacturer | Device Name | 510(k) Number |
|---|---|---|
| Rinovum Women's Health, Inc | The Focus Touch® Conception System | K112200 |

**Reason for Submission:** New Indication for Over-The-Counter Use

**Description of Device**

The Stork® OTC package includes: one Instructions for Use, one Conceptacle® and one plastic applicator.

Once the couple has decided to attempt to become pregnant, the Stork® OTC Conception System Instruction for Use recommends using the device during female's most fertile days in a given month. During sexual intercourse, semen will be collected using the *Conceptacle®*, a cervical cap that is

pre-inserted into a condom-like sheath. The male removes the *Conceptacle®* from the penis by rolling it down and separating it from the penis. After removal, the rim of the cervical cap is lightly pinched so that the Condom-like Sheath can be separated. (The Cervical Cap and Condom-like Sheath are separated in two separate parts). The semen is contained in the cervical cap and its reservoir. The second component, the Applicator, is used for ease of transition of the Cervical Cap to the cervix. The applicator seals the Cervical Cap and contains the semen for transition through the vaginal tract, assisting the female in guiding the cap to the cervix and releasing the semen and the cap in front of the cervix. When the cervical cap is loaded onto the applicator (while it is still outside of the body), The Retainer also has a removal cord that is attached for withdrawal.

**Indications for Use**

The Stork® OTC is indicated for over-the-counter home use by couples who have been unable to conceive naturally and who have received a diagnosis of low sperm count, sperm immobility or unfavorable vaginal environment. The Stork® OTC contains a cervical cap inside a condom-like silicone sheath. It is used to collect semen into a cervical cap then deliver it to the outside of the cervix as an aid to conception. The Stork® OTC should be used during the ovulatory phase of the menstrual cycle.

**Comparison between predicate and proposed device**
The tables below compare the two devices:

| | **PREDICATE DEVICE:** | **PROPOSED DEVICE:** |
|---|---|---|
| | **Focus Touch® Conception System** | **The Stork® OTC** |
| **MANUFACTURER** | Rinovum Women's Health (formerly Intimate bridge 2 Conception, Inc.) | Same as K112200 |
| **510(k) NUMBER** | K112200 | K140186 |
| **REGULATION NUMBER** | 884.5250 Cervical Cap: | Same as K112200 |
| **FDA PRODUCT CODE** | OBB | Same as K112200 |
| **CLASSIFICATION** | II | Same as K112200 |

| | PREDICATE DEVICE: | PROPOSED DEVICE: |
|---|---|---|
| | **Focus Touch® Conception System** | **The Stork® OTC** |
| **INDICATIONS FOR USE** | The Focus Touch™ Conception System is indicated for assisted insemination in instances where low sperm count, sperm immobility, or hostile vaginal environment has been diagnosed. The system (cervical cap in a condom-like silicone sheath) is used to collect semen into a cervical cap, and then deliver the cap to the outside of the cervix as an aid to conception. It is to be used at home following physician instruction. The Focus Touch Conception System should not be left in place for longer than 6 hours. | The Stork® OTC is indicated for over-the-counter home use by couples who have been unable to conceive naturally and who have received a diagnosis of low sperm count, sperm immobility or unfavorable vaginal environment. The Stork® OTC contains a cervical cap inside a condom-like silicone sheath. It is used to collect semen into a cervical cap then deliver it to the outside of the cervix as an aid to conception. The Stork® OTC should be used during the ovulatory phase of the menstrual cycle. |
| **CONTRAINDICATIONS FOR USE** | This product is not for use by those for which it is medically unsafe to have sexual intercourse or to become pregnant. | Same as K112200 |
| **INTENDED ENVIRONMENT FOR USE** | Prescription Home Use Device | Over the Counter (OTC) Home Use Device |
| **PATIENT POPULATION** | Adult | Same as K112200 |

| | PREDICATE DEVICE: | PROPOSED DEVICE: |
|---|---|---|
| | **Focus Touch® Conception System** | **The Stork® OTC** |
| **TECHNOLOGY** | Cervical Cap Insemination with an applicator for delivery and placement. A removal string for cervical cap withdrawal. | Same as K112200 |
| **MATERIAL**[1] | | |
| Cervical Cap | Liquid Silicone Rubber (LSR) 10:1, Implant Grade, Cured | Same as K112200 |
| Condom Sheath | Liquid Silicone Rubber (LSR) 10:1, Implant Grade, Cured | Same as K112200 |
| Retainer | Acetal Copolymer | Same as K112200 |
| Applicator | Acetal Copolymer | Same as K112200 |
| Removal Cord Tether | Polyester USP Suture Material | Same as K112200 |
| **BIOCOMPATIBILITY** | Devices met requirements of ISO 10993-1: 2009 for Sensitization, Cytotoxicity and Irritation | Same as K112200 |
| **STERILITY** | Non-sterile | Same as K112200 |
| **PACKAGING** | The system can be purchased packaged in a quantity of one (1) or three (3) systems per package. | The system can be purchased packaged in a quantity of one (1) |
| **SINGLE USE** | Yes | Same as K112200 |
| **CONDOM/CONCEPTACLE (SEMEN COLLECTION) SHEATH OUTSIDE DIAMETER** | 1.378" +/-.046" | Same as K112200 |

| | PREDICATE DEVICE: | PROPOSED DEVICE: |
|---|---|---|
| | **Focus Touch® Conception System** | **The Stork® OTC** |
| **OVERALL LENGTH OF CONDOM/ CONCEPTACLE** | 7.429" +/-.120" (estimated tolerance - overall length is comprised of 3 separately toleranced dimensions" | Same as K112200 |
| **OVERALL CAP LENGTH (WHEN CONCEPTACLE IS SEPARATED FROM CONDOM)** | 1.67"±.010" | Same as K112200 |
| **SEMEN RESERVOIR DIMENSIONS** | .500±.010" diameter X .800±.010" deep | Same as K112200 |
| **REMOVAL CORD LENGTH** | Loop positioned at 6.50" from the Cap Rim | Same as K112200 |
| **DELIVERY DEVICE LENGTH** | 9.05" – 9.45" | Same as K112200 |
| **DELIVERY DEVICE MAXIMUM INSERTABLE OUTER DIAMETER** | 0.984" | Same as K112200 |

**Technological Characteristics**

Please refer to the comparison table above to see a listing of technological features between the new and predicate device. No new technologies were introduced; therefore, no new questions of safety or efficacy are raised.

**Indication for Use Comparison**

The indications for use between the predicate and proposed device differ in that the proposed device is indicated for over-the-counter use of the device rather than prescription use. The indication for use includes the same user group as the predicate, having the diagnoses of low sperm count, sperm immobility or unfavorable vaginal environment. It also includes further specification for users that have not been able to successfully conceive naturally. Further, the device labeling includes the same warnings and precautions. Studies were completed to demonstrate that the over-the-counter user population could sufficiently self-select and comprehend the labeling. The usability and safety clinical trial demonstrated that users could effectively and safely use the device without physician instruction, overview or intervention, and in accordance with the instructions for use. Therefore, the differences between the indications for use do not represent a new Intended Use. Nor do these differences present new concerns of safety and efficacy.

**Performance Testing - Clinical**

A self-selection study and labeling comprehension study were performed to demonstrate that users could determine the uses of the device, the target population for device use, and if the labeling was clear and understandable. Additionally, a simulated use study was performed to verify that users could follow instructions under simulated-use conditions. All primary endpoints were achieved in all three sections of the study: Self-selection, labeling comprehension, and simulated use.

Following successful completion of the self-selection, labeling comprehension, and simulated use study and the finalization of labeling, clinical human factors and usability testing was performed to validate the instructions for use and demonstrate the proper use placement of

and the safety of the device for users. All subjects were able to use the device to collect semen, effectively position and place the Conceptacle® in the vaginal tract using the applicator, and remove the cervical cap from the vaginal tract. These steps were successfully completed without any evidence of trauma or injury to the vaginal tract or cervical os. These endpoints were verified by visual inspection and physical examination by the primary investigator.

Primary Self-Selection and Labeling Comprehension Endpoints:

- Understanding the Indications for Use
- Understanding the Selection of the Device
- Understanding the Contraindications for Use
- Understanding Warnings
- Understanding When to Use the Device
- Understanding Activity Limitations While Wearing the Cervical Cap
- Understanding that the Device Does Not Guarantee Pregnancy
- Understanding How Long To Use the Device Without Successful Results Before Contacting a Physician

Primary Simulated Use / Usability Endpoints (Male):

- Correctly Place the Conceptacle on a Penis
- Correctly Remove the Conceptacle from a Penis
- Correctly Separate the Condom from the Cervical Cap
- Collect and Contain Semen Using the Conceptacle (Usability only)

Primary Simulated Use / Usability Endpoints (Female):

- Correctly Place the Cervical Cap in the Applicator
- Correctly Close the Applicator
- Correctly Insert the Applicator into a Vaginal Tract
- Correctly Position the Applicator Near the Cervical Os
- Correctly Open the Cervical Cap with the Applicator
- Correctly Engage the Trigger Button to Release the Cervical Cap
- Leave the Cap in Place as Directed (Usability only)
- Correctly Avoid Sexual Activity While the Cervical Cap is in Place (Usability only)
- Correctly Withdraw Device from the Vaginal Tract
- Correctly Treat the Device as Single Use

**Performance Testing – Bench**

Biocompatibility Testing was performed on the device to support the applicator color changes from the predicate device. Testing demonstrated that the Stork® OTC materials are considered non-cytotoxic, non-irritating, and non-sensitizing. Colorant safety was deemed acceptable through additional Colorant Leachables Testing and a resulting Toxicological Risk Assessment of Extractable Chemicals. Bench testing demonstrated that the pull strength of the withdrawal cord was met for all systems tested

and a shelf life study was performed to verify that all components of the Stork® OTC were shown to function properly and according to their design intent following a 6 month shelf life test. The Stork® OTC Conceptacle is identical to the predicate and data from the predicate device was used for the following aspects:

- Human Sperm Survival Assay (HSSA)
- Condom Mechanical Testing
- Shelf-life

**Conclusions**

The Stork® OTC is substantially equivalent to the Focus Touch® Conception System. The Stork® OTC has the same intended uses, technological characteristics, and principles of operation as its predicate device. The differences between The Stork® OTC and the Focus Touch® Conception System raise no new issues of safety or effectiveness. Usability and Clinical data demonstrate that The Stork® OTC is as safe and effective as the Focus Touch®. Thus, The Stork® OTC is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 11, 2014

Rinovum Women's Health, Inc.
Andrew Zeltwanger
Director of Regulatory & Quality
300 Oxford Drive, Suite 330
Monroeville, PA 15146

Re: K140186
Trade/Device Name: The Stork® OTC
Regulation Number: 21 CFR§ 884.5250
Regulation Name: Cervical Cap
Regulatory Class: II
Product Code: OBB
Dated: June 10, 2014
Received: June 11, 2014

Dear Andrew Zeltwanger,

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Glen D Bell -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement on last page.*

510(k) Number *(if known)*
K140186

Device Name
The Stork® OTC

Indications for Use *(Describe)*

The Stork® OTC is indicated for over-the-counter home use by couples who have been unable to conceive naturally and who have received a diagnosis of low sperm count, sperm immobility or unfavorable vaginal environment. The Stork® OTC contains a cervical cap inside a condom-like silicone sheath. It is used to collect semen into a cervical cap then deliver it to the outside of the cervix as an aid to conception. The Stork® OTC should be used during the ovulatory phase of the menstrual cycle. The Stork® OTC Cervical Cap should not be left in place for longer than six hours.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

for Ben R Fisher

Glenn B. Bell -S



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# Product Classification

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| | |
|---|---|
| **Device** | Kit, Conception-Assist, Home Use |
| **Definition** | The kit is intended 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 more than 6 hours. The kit consists of: conception (cervical) caps; 3 polyurethane condoms; 24 ovulation predictors; 3 pregnancy test kits; 3 "sperm friendly" moisturizer samples (Pre Lubricant); 1 conception journal; 1 instruction manual; 2 conception wheels (1 in English and 1 in French); 1 medical provider envelope. |
| **Physical State** | The Kit consists of : conception (cervical) caps (1 for practice insertions); 3 polyurethane condoms; 24 ovulation predictors; 3 pregnancy test kits; 3 "sperm friendly" moisturizer samples (Pre Lubricant); 1 conception journal; 1 instruction manual; 2 conception wheels (1 in English and 1 in French); 1 medical provider envelope. All device contents have been previously cleared through pre-market notifications; however, the condom and cervical cap have new indications for use (semen collector and collection cap respectively). |
| **Technical Method** | During sexual intercouse, sperm is collected in a polyurethane semen collection device (condom). Immediately thereafter, this sperm is transferred to the bowl of a cervical cap (made of silicone elastomers). This cap is placed on the cervix for up to 6 hours, so as to improve the chances of insemination. |
| **Target Area** | Sperm, uterine horn, vagina and embryo (if any) have the potential to be affected by this device. |
| **Regulation Medical Specialty** | Obstetrics/Gynecology |
| **Review Panel** | Obstetrics/Gynecology |
| **Product Code** | OBB |
| **Premarket Review** | GastroRenal, ObGyn, General Hospital, and Urology Devices[6] (OHT3)<br>Reproductive, Gynecology and Urology Devices (DHT3B) |
| **Submission Type** | 510(k) |
| **Regulation Number** | 884.5250 |
| **Device Class** | 2 |
| **Total Product Life Cycle (TPLC)** | TPLC Product Code Report[7] |
| **GMP Exempt?** | No |
| **Summary Malfunction Reporting** | Eligible |
| **Implanted Device?** | No |
| **Life-Sustain/Support Device?** | No |
| **Third Party Review** | Not Third Party Eligible |

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Page Last Updated: 08/07/2023

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