DEC 19 2012

510(k) SUMMARY

Device Name: Ontex Unscented Digital and Plastic and Cardboard Applicator Tampons

Name Address Telephone number of submitter, contact person dated 12/14/12
Robert J Staab, Ph.D. for Ontex bvba as Official Correspondent
RTA, Inc., 30 Neck Road, Old Lyme CT 06371
860 434 5872

Ontex bvba
Genthof5
9255 Buggenhout
Belgium

The registration number is 3003293044

Regulation number, Regulation name, Classification, product code for Ontex tampons
OBGYN Panel, Unscented Menstrual Tampons, 21 CFR 884 5470, PRODUCT CODE HEB

Predicate Device: Ontex Organic Tampons, K090819

Indications for Use:
The Ontex Unscented Digital and Plastic and Cardboard Applicator Tampons, Available in light, regular, super, and super plus absorbency are inserted into the vagina and used to absorb menstrual or other vaginal discharge.

Device description:
The Ontex Tampons are:

1) Unscented Digital
2) Unscented Plastic Applicator
3) Unscented Cardboard Applicator

Both the Applicator and Digital Tampons are inserted into the vagina to absorb menstrual or other vaginal discharge.

These tampons, both the digital types and the applicator types will be provided with 4 absorbencies: light (<6g), regular (6-9g), super, (9-12g), and super plus (12-15g)

These Tampons are made from viscose and/or cotton cellulosic material and polymeric overwrap and cotton or cotton polyester cord. Applicators are either polyethylene or polypropylene.

The materials used in these tampons are similar to those used in other legally marketed tampons..

Technological Characteristics

To compare the Predicate Device:

- The pledget/wadding material has been changed from 100% organic cotton to 100% rayon.
- The overwrap material has been changed from 100% organic cotton to polyethylene/polypropylene for applicator tampons.
- On digital tampons 100% rayon an overwrap Polyethylene/polyester is needed where not needed on digital tampons 100% organic cotton.
- The withdrawal cord was changed from 100% organic cotton to 67% polyester and 33% cotton
- Light and Super Plus absorbencies were added to the paper applicator tampons.
- A Light absorbency was added to the digital tampons.
- A compact size polyethylene applicator version was added
- A full size (long) polyethylene applicator version was added.

Assessment of Performance Standards: Not Applicable

Non-Clinical Testing: Biocompatibility testing and safety evaluations of tampon components were carried out for acute systemic toxicity, irritation, vaginal irritation.

Clinical testing: Skin allergy was tested using human repeated insult patch testing.

Conclusions

The results of these tests demonstrate that these Tampons are equivalent in terms of safety and effectiveness to legally marketed tampons. Standard Syngyna testing confirmed the absorbency of these Tampons. The review of existing toxicological data in the public literature, confirms the safety of these standard tampons.

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

December 19, 2012

Ontex bvba
% Robert J. Staab, Ph.D.
President
RTA, Inc.
30 Neck Road
OLD LYME CT 06371

Re: K122603
Trade/Device Name: Ontex Unscented Digital and Plastic and Cardboard Applicator Tampons
Regulation Number: 21 CFR§ 884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: HEB
Dated: December 17, 2012
Received: December 18, 2012

Dear Dr. Staab:

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,

Benjamin R. Fisher -S

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

Indications for Use

510(k) Number (if known): _K122603

Device Name: Ontex Unscented Digital and Plastic and Cardboard Applicator Tampons,

Indications for Use:

The Ontex Unscented Digital and Plastic and Cardboard Applicator Tampons, Available in light, regular, super, and super plus absorbency are inserted into the vagina and used to absorb menstrual or other vaginal discharge.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
2012.12.19 14:28:41 -05'00'

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122603