JUL 2 9 2009

K092054

510(k) Summary of Safety and Effectiveness

The MOXIE Plastic Applicator and Non Applicator Tampons are identical to MAXIM Plastic Applicator and Non Applicator tampons under K080775. The information below is identical to that approved for the MAXIM devices under K080775.

Device name (trade names):

MOXIE Compact, Plastic Applicator, Regular , Super, Super plus and Ultra

MOXIE Non Applicator, Regular, Super ,Super plus and Ultra

Classification name

Unscented menstrual tampons

Device description

The MOXIE tampons are used to absorb menstrual fluid.

The MOXIE series tampons come with a plastic applicator and without a plastic applicator in sizes: Regular, Super ,Super plus and Ultra.

The MOXIE tampons are made of commercial cotton and rayon, a polyethylene/polyester cover, and cotton or rayon string.

Equivalence to a legally marketed device

The MOXIE Plastic Applicator tampons are substantially equivalent to current commercilly marketed TAMPAX COMPAK, COMPACT PLASTIC APPLICATOR and the MOXIE Non Applicator Tampons are substantially equivalent to o.b.® Non Applicator Tampons.

Intended use

The MOXIE unscented menstrual tampon is intended for intravaginal absorption of menstrual or other vaginal discharge.

This is the same intended use as current commercial tampons.

Technological

There are no differences between the technical characteristics of the MOXIE tampons and the predicate characteristic of the substantial equivalent devices MAXIM tampons under K080775.

Biocompatibility

Biocompatability and microbiological testing has been conducted on tampons made with these commercial materials. The results of these tests demonstrate that the Moxie tampons are equivalent to legally marketed tampons. This testing included :

- Microbiological testing
- Clinical Testing

Results of preclinical and clinical testing indicate that the safety of the modified tampon is comparable to current legally marketed, commercial tampons.

Conclusion

The MOXIE Plastic Applicator Tampons and Moxie Non Applicator Tampons are identical to MAXIM Plastic Applicator Tampons and MAXIM Non Applicator Tampons approved for market under K080775.

Contact

Submitted by Tosama d.d., Šaranovičeva cesta 35, Vir, 1230 Domžale, Slovenia

Contact person: Antonija Videnšek / +386 (0) 1 729 03 70

Signed by Quality Manager Antonija Videnšek

Date : June 19, 2009

Exhibit 116 005

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 9 2009

Ms. Antonija Videnšek
Quality Manager
TOSAMA d.d.
Tovarna sanitetnega materiala d.d.
Vir, Šaranovičeva cesta 35
1230 Domžale
SLOVENIA

Re: K092054
Trade/Device Name: MOXIE Plastic Applicator Tampon &
MOXIE Non-Applicator Tampon
Regulation Number: 21 CFR §884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: HEB
Dated: June 22, 2009
Received: July 7, 2009

Dear Ms. Videnšek:

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 (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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510K Number (if known): K092054

Device Name:

MOXIE Plastic Applicator Tampon & MOXIE Non-Applicator Tampon

Indications for Use:

The MOXIE tampons (both types) are unscented tampons for:

• Women's personal hygiene with respect to intra vaginal absorption of menstrual or other vaginal discharge.

• The plastic applicator is for easing the placement of the tam pon correctly into the vagina (only the MOXIE Plastic Applicator Tampon).

Prescription Use _____ AND/OR Over-The Counter Use ___X_____

(Part 21CFR 801 Subpart C) (Optional Format 1-2- 96)

(Part 21 CFR 801 Subpart O)

(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 K092054

Exhibit 116 006