K080775

SEP 1 0 2008

510(k) Summary of Safety and Effectiveness

Device name (trade names):	Maxim Compact, plastic Applicator, Regular & Super Maxim Compact, plastic Applicator, Super plus & Ultra Maxim Non Applicator, Regular & Super Maxim Non Applicator, Super plus & Ultra
Classification name	Unscented menstrual tampons
Device description	The Maxim tampons are used to absorb menstrual fluid. The Maxim series tampons comes with plastic applicator and without in sizes: Regular, Super, Super plus, Ultra. The Maxim tampons are made of commercial cotton and rayon, a polyethylene/polyester cover, and cotton or rayon string.
Equivalence to a legally marketed device	The Maxim tampons are substantially equivalent to current commercial TAMPAX COMPAK, COMPACT PLASTIC APPLI. SUPER TAMPO And o.b.® Non-applicator Tampons.
Intended use	The Maxim 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	The only difference between the modified ob® tampons and the predicate characteristics tampons is the absorbency has increased to 15-18 grams absorbency measured by the syngyna test method (21 CFR 801.430). This is accomplished by slight increases in the weight and dimensions of the tampons
Biocompatibility	Biocompatability and microbiological testing has been conducted on tampons made with these commercial materials. The results of these tests demonstrate that the Maxim tampons are equivalent to legally marketed tampons. This testing included : • Microbiological testing • Clinical Testing
Conclusion	Results of preclinical and clinical testing indicate that the safety of the modified tampon is comparable to current legally marketed, commercial tampons.
Contact	Submitted by Tosama d.d., Saranoviceva cesta 35, Vir, 1230 Domzale, Slovenia Contact person: Antonija Vidensek / +386 (0) 1 729 03 70
Date	This Summary was prepared on October 20., 2007

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 0 2008

Tosama d.d.
% Mr. Harry van Vugt
Responsible Third Party Official
KEMA Quality B.V.
4377 County Line Road
CHALFONT PA 18914

Re: K080775
Trade Name: MAXIM Plastic Applicator Tampon & MAXIM Non-Applicator Tampon
Regulation Number: 21 CFR 884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: HEB
Dated: August 21, 2008
Received: August 26, 2008

Dear Mr. van Vugt:

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 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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Joyce M. Whang, Ph.D.
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): K080775

Device Name: MAXIM Plastic Applicator Tampon & MAXIM non-Applicator Tampon

Indications for Use:

The MAXIM 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 tampon correctly into the vagina (only the MAXIM Plastic Applicator Tampon).

Prescription Use	AND/OR	Over-The Counter Use
(Part 21CFR 801 Subpart D)		(Part 21CFR 801 Subpart C) (Optional Format 1-2-96)
		X

(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 K080775