JUN 23 2010

Section C 510(k) Summary (21 CFR 807.92)

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K092781

(a) (1) The summary contains on the first page, preferably on your letterhead paper, the submitters name, address, phone and fax numbers, name of contact person, and date the summary was prepared:

Submitter' s name:	MAM International AG
Submitter' s address:	Wilenstraße 17 8832 Wollerau, Schwyz Switzerland
Contact Name:	Markus Schoell
Phone No.:	0043-1-49141-715
Fax No.:	0043-1-49141-719
Facility Registration No.:	3003296982
Owner Operator No.:	9054867
Date of Summary:	23.07.2009

(a) (2) The name of the device, including the trade or proprietary name if applicable, the common or usual name and the classification name if known:

Device Name/ Trade Name::	MAM Twister
Classification Name:	Fluid-Filled Teething Ring
Device Classification:	II
Regulation Number:	872.5550
Panel:	Dental
Product Code :	KKO

(a) (3) An identification of the legally marked device to which your firm is claiming substantial equivalence:

Class II Fluid-Filled Teething Ring (Teether with waterfilled part) that that meets requirements of USP <61>, ASTM F963 section 4.3.6.1 & 4.3.6.3, 16 CFR 1303 - Ban of lead-containing paint (< 90 ppm), CPSIA Sec.101: general lead ban - lead in substrate (< 100 ppm), 16 CFR 1500 - Mechanical Hazards, ASTM F963 – toy standard, 16 CFR 1500.44 - Flammability of solids, 16CFR1501 - Small part requirement, CPSIA Sec.108 & CA Bill 1108 - Ban on phthalates (DEHP, DBP, BBP, DINP, DIDP, DnOP < 0,1%), 16 CFR 1500.52(c) - Bite test, EN 71-1, EN 71-3 & EN 71-9

Predicate device:
WATER FILLED TEETHER, ROYAL INDUSTRIES (THAILAND) PUBLIC CO. LTD. K052105

(a) (4) A description of the device:

Class II Fluid-Filled Teething Ring (Teether with waterfilled part) that that meets requirements of USP <61>, ASTM F963 section 4.3.6.1 & 4.3.6.3, 16 CFR 1303 - Ban of lead-containing paint (< 90 ppm), CPSIA Sec.101: general lead ban - lead in substrate (< 100 ppm), 16 CFR 1500 - Mechanical Hazards, ASTM F963 – toy standard, 16 CFR 1500.44 - Flammability of solids, 16CFR1501 - Small part requirement, CPSIA Sec.108 & CA Bill 1108 - Ban on phthalates (DEHP, DBP, BBP, DINP, DIDP, DnOP < 0,1%), 16 CFR 1500.52(c) - Bite test, EN 71-1, EN 71-3 & EN 71-9

(a) (5) The Summary describes the intended use of the device

Device Intended Use: The MAM Twister Teether was developed for the needs of babies who are having their first teeths. It is designed to offer optimum comfort and safety for the baby and offers all the soothing textures and cooling comfort in order to ease babies teething pain.

(a) (6) A Summary of the technological characteristics of new device compared to the predicate device:

The MAM Twister is summarized with the following technological characteristics compared to ASTM or equivalent standard

Characteristics	Standard	Device performance
Bacteriological	USP <61> / ASTM F963 section 4.3.6.1	Meets
Cleanliness of products used in toys	ASTM F963 section 4.3.6.3	Meets
Ban of lead-containing paint	16 CFR 1303	Meets (< 90 ppm)
General lead ban - lead in substrate	CPSIA Sec.101	Meets (< 100 ppm)
Mechanical Hazards	16 CFR 1500	Meets
Mechanical Hazards	ASTM F963 section 8.6 - 8.10	Meets
Flammability of solids	16 CFR 1500.44	Meets
Dimension - Small part requirement	16CFR1501	Meets
Ban on phthalates	CPSIA Sec.108 & CA Bill 1108	Meets
Mechanical Hazards – Bite Test	16 CFR 1500.52(c)	Meets
Safety of toys	EN 71-1, EN 71-3 & EN 71-9	Meets

(b) (1) A brief discussion of the nonclinical submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalence:

The MAM Twister Teether meets requirements of USP <61>, ASTM F963 section 4.3.6.1 & 4.3.6.3, 16 CFR 1303 - Ban of lead-containing paint (< 90 ppm), CPSIA Sec.101: general lead ban - lead in substrate (< 100 ppm), 16 CFR 1500 - Mechanical Hazards, ASTM F963 – toy standard, 16 CFR 1500.44 - Flammability of solids, 16CFR1501 - Small part requirement, CPSIA Sec.108 & CA Bill 1108 - Ban on phthalates (DEHP, DBP, BBP, DINP, DIDP, DnOP < 0,1%), 16 CFR 1500.52(c) - Bite test, EN 71-1, EN 71-3 & EN 71-9

(b) (2) A brief discussion of the clinical submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalence:

Clinical data is not needed for Fluid Filled Teethers for devices cleared by the 510 (k) process.

(b) (3) The conclusion drawn from the nonclinical tests that demonstrate that the device is as safe, as effective, and performed as well or better than the legally marketed device identified in (a) (3):

It can be concluded that the MAM Twister Teether meet all above mentioned tests so FDA 510(k) approval shall be issued for this product

(c) (1) Additional questions which was answered by MAM regarding 510(k) pre-market notification of The MAM Twister dossier: K092781

Please find additional information in the general document
"MAM Twister_K092781_ additional question_FDA_summary"

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JUN 23 2010

MAM International AG
C/O Mr. Michael Tedesco
MAM USA Corporation
Corporate Park Drive 106
White Plains, New York 10604

Re: K092781
Trade/Device Name: MAM Twister
Regulation Number: 21 CFR 872.5550
Regulation Name: Teething Ring
Regulatory Class: II
Product Code: KKO
Dated: June 16, 2010
Received: June 17, 2010

Dear Mr. Tedesco:

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,

Anthony D. Watson, BS, MS, MBA
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

(4)

INDICATIONS FOR USE FORM

INDICATIONS FOR USE

510(K) Number (if known): K092781

Device Name: MAM Twister

Indications for Use:

The MAM Twister Teether was developed for the needs of babies who are having their first teeths. It is designed to offer optimum comfort and safety for the baby and offers all the soothing textures and cooling comfort in order to ease babies teething pain.

Prescription Use_____ AND/OR Over-The-Counter Use ✓

(Part 21 CFR 801 Subpart D) (21 CRF 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulay for MSE

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092781