

K123855

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MAY 24 2013

Date Prepared 11-Dec-12

Solid Toy Ind. Ltd.
No. 39, Pengfei Road, Pengcheng Community, Dapeng Town, Longgang District
Shenzhen City, Guangdong Province, China

Tel - 86-755-84315188
Fax - 86-755-84315979

Official Contact: John Chow – Managing Director

Proprietary or Trade Name: Water-Filled Teether

Common/Usual Name: Fluid-filled teething rings

Classification Code/Name: KKO – Fluid-filled teething ring
21 CFR 872.5550
Class 2

Predicate Devices: K992384 - Stevenson CPAP/Pro

Device Description:

The proposed Water-filled teether is a simple plastic shaped device which is filled with water. It may be placed in a refrigerator to be cooled and then provided to the teething baby to help soothe any pain from teething. This is an OTC device.

Indications for Use:

Indicated to soothe and cool teething babies and help reduce teething pain.

Patient Population: Teething babies

Environment of Use: Home

Predicate Device Comparison:

The Water-Filled Teether is viewed as substantially equivalent to the predicate device because:

Indications –

- The indication to soothe and cool teething babies and help reduce teething pain is identical to the predicate.
Discussion - Identical to MAM Teether (K092781)

Patient Population –

- For teething babies
Discussion - Identical to MAM Teether (K092781)

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Technology –

- The use of a water filled ring is the identical technology to the predicate.

Discussion - Identical to MAM Teether (K092781)

Materials –

- The materials in patient contact have been tested per ISO 10993-1 as direct communicating, mucosal, prolonged contact for cytotoxicity, sensitization, and irritation.

Discussion - Identical to MAM Teether (K092781)

Environment of Use and OTC –

- The environment is home use and OTC.

Discussion - Identical to MAM Teether (K092781)

Differences –

There are no differences between the predicate and the proposed device which would raise any new safety or risks and thus can be found to be substantially equivalent.

Attributes	Water-Filled Teether	MAM Teether
Indications for Use	Indicated to soothe and cool teething babies and help reduce teething pain.	Developed for the needs of babies who are having their first teeth. It is designed to offer optimum comfort and safety for the baby and offers all soothing textures and cooling comfort in order to ease babies teething pain.
Patient Population	Teething babies	Teething babies
Environment of Use	Home	Home
Prescriptive	No – OTC	No – OTC
Water-filled	Yes	Yes
Materials	Tested per ISO 10993-1 as Direct communication, mucosal, prolonged contact Cytotoxicity Sensitization Irritation	Same
Characteristics		
Bacteriological	ASTM F963 – 4.3.6.1	ASTM F963 – 4.3.6.1
General lead ban – lead in substrate	CPSIA Sec 101	CPSIA Sec 101
Mechanical Hazards	16 CFR 1500	16 CFR 1500
Flammability of solids	16 CFR 1500	16 CFR 1500
Small part requirements	16 CFR 1501	16 CFR 1501
Ban on Phthalates	CPSIA Sec 108, CA prop 65	CPSIA Sec 108, CA prop 65
Bite test	16 CFR 1500.52(c)	16 CFR 1500.52(c)

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Non-clinical Testing Summary -

Biocompatibility of Materials –

Materials were evaluated per ISO 10993-1. There are parts and thus their respective materials which have the following patient contact and duration.

The device is consider Direct communicating, Mucosal, Prolonged contact which require the following tests.

- Cytotoxicity (tested per ISO 10993-5)
- Sensitization (tested per ISO 10093-10)
- Irritation (tested per ISO 10993-10)
- Pass / fail criteria was for the each respective ISO 10993 test

Discussion –

All materials were tested according to ISO 10993-1 for the appropriate level of patient contact and duration and found to pass the applicable ISO 10993-1 test requirements.

We performed the following tests:

Standard	Test
16 CFR 1500 – Mechanical Hazards	1500.51(b) Impact Test
	1500.52 Bite test
	1500.53(e) Torque Test
	1500.53 (f) Tension Test
	1500.53 (g) Compression Test
	1500.3(c)(6)(vi) Flammable solid
	1500.3(c)(6)(iii) Combustible
16 CFR 1501 – FHSA	Small part requirement
ASTM F963-08 Standard consumer safety for toys	4.1 Material Quality 4.6 Small Objects 4.7 Accessible Edges 4.9 Accessible Points 4.22 Teethers and Teething Toys 5.16 Promotional materials 6.1 Definition and description 7.1 Producer's name and address Drop Test
CPSIA 2008 And CA Prop 65 And IL PA 095-1019	Total lead content

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Standard	Test
CPSIA And CA Prop 65	108(a) Phthalates BBP/DBP/DEHP/DnHP/DIDP
	108(b)(1) Phthalates DNOP/DINP/DIDP
ASTM F963-08	Sec 4.3.6.1 USP Purified water
	Total Cadmium
	Soluble Heavy metals
	BPA

Substantial Equivalence Conclusion -

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to be 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

May 24, 2013

Solid Toy Ind. Limited
C/O Mr. Paul E. Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
BONITA SPRINGS FL 34134

Re: K123855
Trade/Device Name: Water-Filled Teether
Regulation Number: 21 CFR 872.5550
Regulation Name: Teething Ring
Regulatory Class: II
Product Code: KKO
Dated: April 5, 2013
Received: April 8, 2013

Dear Mr. Dryden:

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 contact 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Digitally signed by Mary S. Runner: DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary S. Runner, s=0.9.2342.19200300.100.1.1=130008795
Mary S. Runner, DDS, MBA
Date: 2013.05.31 14:41:28 -0400

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

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510(k) Number:

K123855
(To be assigned)

Device Name:

Water-Filled Teether

Indications for Use:

Indicated to soothe and cool teething babies and help reduce teething pain.

Prescription Use
(Part 21 CFR 801 Subpart D)

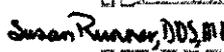
or

Over-the-counter use XX
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Mary S. Runner -S
DN: c=US, o=U.S. Government,
ou=HHS, ou=FDA, ou=People,
cn=Mary S. Runner -S,
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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