K071178

JUN 22 2007

SECTION 5 - 510(K) SUMMARY

OTOMEDICS SOFT TYMPANOSTOMY TUBE

510(k) Number K_____

Applicant's Name:

Company name:	Otomedics Advanced Medical Technologies Ltd.
Address:	8 Bialik St. Jerusalem, Israel 96221
E-mail:	cohen@otomedics.com yossi@otomedics.com
Tel:	+ 972 50 8685888
Fax:	+972 2 6510808

Contact Person:

Contact Name:	Ahava Stein
Company:	A. Stein – Regulatory Affairs Consulting
Address:	20 Hata'as St. (P.O.B. 124) Kfar Saba 44425 ISRAEL
Tel.:	+972 (9) 7670002
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E-mail:	asteinra@netvision.net.il

Date Prepared:

Date: April 22, 2007

Name of the device:

Soft Tympanostomy Tube

Trade or proprietary name, if applicable:

Otomedics Soft Tympanostomy Tube

Common or usual name:

Tympanostomy Tube,

Establishment Registration No.: Otomedics will submit form FDA 2891 (Initial Registration of Medical Device Establishment) for its operations at the above address and will submit Form FDA 2892 (Device Listing) for the product.

Classification Name:

21 CFR classification code 874.3880 Tympanostomy tube (product code ETD).

Classification:

Tympanostomy tube is a CLASS II medical device. The classification panel is the Prosthetic Devices Panel

Predicate Device:

The Otomedics *Soft* Tympanostomy Tube (STT) is similar to Goode T-Tubes (K852387 Manufactured by Xomed, Inc.), the Touma II T-Tube (K941407 Xomed – Treace Inc), the Armstrong Grommet (K822375 Manufactured by Xomed-Treace, Inc), the Straight Shank (510(k) K781257) Xomed Inc) and the Umbrella Tube (K791680 Xomed Inc) in the intended use and in technological characteristics of the devices.

Device Description:

The Otomedics STT is a single flexible tube made of silicone rubber. The internal shape of the shaft is conical with T-shaped external flanges.

Intended Use / Indication for Use:

Otomedics STT is a device that is intended to be implanted for ventilation or drainage of the middle ear.

Substantial Equivalence:

The Otomedics STT has the same intended use as the predicate devices. The Otomedics STT has the same technological characteristics, (i.e., same materials, same basic design and principles of operation) as the predicate Goode T-Tube, Touma II T-Tube, Armstrong Grommet, Straight Shank and Umbrella Tube. The differences in the new device do not raise new issues of safety or effectiveness.

Therefore, we believe that the Otomedics STT is substantially equivalent to the predicate devices cited above and therefore may be cleared for marketing in the United States.

COMPARISON TABLE

	***Soft* Tympanostomy Tube**	**Goode T-Tubes®**	**Touma II T-Tube**	**Armstrong Grommet**	**Straight Shank**	**Umbrella Tube**
Manufacturer name	Otomedics Advanced Medical Technologies Ltd	Xomed, Inc.	Xomed – Treace Inc	Xomed – Treace Inc	Xomed Inc	Xomed Inc
Classification Code	ETD	ETD	ETD	ETD	ETD	ETD
Intended use	Short and Long Term	Short and Long Term	Short and Long Term	Short and Long Term	Short and Long Term	Short and Long Term
Material	Silicon	Activent Silicon	Silicon/Blue	Silicon/Blue	Fluoroplastic/ White	Silicon/Blue
Color	White	White	Blue	Blue	White	Blue
Single use	Yes	Yes	Yes	Yes	Yes	Yes
Flexible	Yes	Yes	Yes	Yes	Yes	Yes
Shape of flange	Arched, flat, asymmetric	Cylindrical, symmetric	Flat, symmetric	Flat, asymmetric	Cylindrical, symmetric	Arched, symmetric

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Otomedics Advanced Medical Technologies, Ltd.
c/o Ahava Stein
Regulatory Affairs Consulting, Ltd.
Beit Hapamon, Box 124
20 Hata'as (Room 213)
Kfar Saba 44425
ISRAEL

JUN 2 2 2007

Re: K071178
Trade/Device Name: Otomedics Soft Tympanostomy Tube
Regulation Number: 21 CFR 874.3880
Regulation Name: Tympanostomy Tube
Regulatory Class: II
Product Code: ETD
Dated: April 22, 2007
Received: April 27, 2007

Dear Mr. Stein:

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 (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

M B Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K071178

SECTION 4 - INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: Otomedics Soft Tympanostomy Tube

Indications for use: **Otomedics Soft Tympanostomy Tube is a device that is intended to be implanted for ventilation or drainage of the middle ear.**

Prescription Use __√__ *OR* *Over-The-Counter Use*___
(Per 21 C.F.R. 801 Subpart D) *(Optional Format Subpart C)*

(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 Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K071178 Date 6/21/07