510(K) SUMMARY
GRACE DYNAMIC OSSICULAR REPLACEMENT PROSTHESES

Trade Name:	Grace Dynamic Ossicular Replacement Prostheses
Common Name:	Ossicular Replacement Prostheses
Classification Name:	Ossicular Replacement Prostheses
510(k) No.:	K091187
Official Contact:	Jeff Cobb Consultant Grace Medical, Inc. 8500 Wolf Lake Drive, Suite 110 Memphis, TN 38133
Telephone:	(901) 380-7000
Telefax:	(901) 380-7001
Date Prepared:	April 20, 2009

Predicate Devices

1. Kurz Aerial TORP manufactured by Heinz Kurz GmbH Medizintechnik and cleared via 510(k) No. K972585.
2. Grace Medical's K-Helix Piston and Porp Partial Ossicular Replacement Prostheses, cleared via 510(k) No. K080070.
3. Grace Medical's Adjustable Length TORP cleared via 510(k) No. K061853.

Intended Use – The Grace Dynamic Ossicular Replacement Prostheses have the same primary intended use as the predicate devices.

An ossicular replacement prosthesis is a device intended to be implanted for the functional reconstruction of segments of the ossicular chain and facilitates the conduction of sound wave from the tympanic membrane to the inner ear. Ossicular replacement prostheses are indicated for the functional restoration of the ossicular chain when a conductive hearing loss is present. Indications for use include:

(a) Chronic middle ear disease,
(b) Otosclerosis,
(c) Congenital fixation of the stapes,
(d) Secondary surgical intervention to correct for a significant and persistent conductive hearing loss from prior otologic surgery, and
(e) Surgically correctible injury to the middle ear from trauma.

Material(s) – The Grace Dynamic Ossicular Replacement Prostheses are manufactured from the same materials as the predicate devices:

(i) Unalloyed titanium (ASTM F67)
(ii) Titanium alloy (ASTM F136)
(iii) Medical Grade Silicone
(iv) ASTM F1185 – Hydroxylapatite

Comparisons

1. The Grace Dynamic Ossicular Replacement Prostheses are similar / dissimilar to the Kurz Aerial TORP in the following ways:

   - Intended use – The Grace Dynamic ORP bridges the gap between footplate and TM or the stapes and TM; whereas, the Kurz TORP bridges the gap between footplate and TM.
   - Materials of construction – both devices contain titanium or titanium alloy; whereas, the Grace Dynamic Ossicular Replacement Prostheses also contains medical grade silicone and hydroxylapatite.

2. The Grace Dynamic Ossicular Replacement Prostheses are similar / dissimilar to the Grace Medical K-Helix Piston in the following ways:

   - Intended use – The Grace Dynamic ORP bridges the gap between footplate and TM or the stapes and TM; whereas, the K-Helix Piston bridges the gap between the footplate and the remnant of the incus.
   - Materials of construction – both devices contain titanium or titanium alloy; whereas, the Grace Dynamic ORP also contains medical grade silicone and hydroxylapatite.

3. The Grace Dynamic Ossicular Replacement Prostheses are similar / dissimilar to the Grace Medical Fixed Length TORP's in the following ways:

   - Intended use – The Grace Dynamic ORP bridges the gap between footplate and TM or the stapes and TM; whereas, the Grace Medical Fixed Length TORP bridges the gap between footplate and TM.
   - Materials of construction – both devices contain titanium or titanium alloy, a medical-grade silicone sleeve, and hydroxylapatite.

Differences between the Grace Dynamic Ossicular Replacement Prostheses and the predicate devices should not affect the safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 14 2009

Grace Medical, Inc.
c/o Mr. Jeff Cobb
Consultant
Regulatory Affairs & Quality
8500 Wolf Lake Drive, Suite 110
Memphis, TN 38133

Re: K091187
Trade/Device Name: Grace Dynamic Ossicular Replacement Prosthesis
Regulation Number: 21 CFR 874.3495
Regulation Name: Total ossicular replacement prosthesis
Regulatory Class: II
Product Code: ETA
Dated: August 4, 2009
Received: August 5, 2009

Dear Mr. Cobb:

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,

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

Enclosure

K091187

510(k) Number:

Device Name: Grace Dynamic Ossicular Replacement Prostheses

Indications for Use:

An ossicular replacement prosthesis is a device intended to be implanted for the functional reconstruction of segments of the ossicular chain and facilitates the conduction of sound wave from the tympanic membrane to the inner ear. Ossicular replacement prostheses are indicated for the functional restoration of the ossicular chain when a conductive hearing loss is present. Indications for use include:

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(e) Surgically correctible injury to the middle ear from trauma.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use _____ (Optional Format 1-2/96)

Daniel C Clapper
(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K091187