### 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

**Grace Medical Adjustable Length and Fixed Length Partial and Total Ossicular Replacement Prostheses**

**Trade Name:** The family of Grace Medical Adjustable and Fixed Length Partial & Total Ossicular Replacement Prostheses consists of:

- Grace Medical ALTO (Adjustable Length Total Ossicular) Prostheses
- Grace Medical ALPO (Adjustable Length Partial Ossicular) Prostheses
- Grace Medical FLTO (Fixed Length Total Ossicular) Prostheses
- Grace Medical FLPO (Fixed Length Partial Ossicular) Prostheses
- Silverstein ALTO (Adjustable Length Partial Ossicular) Prostheses with Footplate Tack
- Grace Medical Frisbee Myringopexy (Fixed Length Partial Ossicular) Prostheses

**Common Name:** Partial Ossicular Replacement Prostheses

**Classification Name:**
- Partial Ossicular Replacement Prostheses (CFR 21 § 874.3450)
- Total Ossicular Replacement Prostheses (CFR 21 § 874.3495)

**Official Contact:**
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Vice President of Regulatory Affairs & Quality  
Grace Medical, Inc.  
8500 Wolf Lake Drive, Suite 110  
Memphis, TN 38133

**Telephone:**  
(901) 380-7000

**Telefax:**  
(901) 380-7001

**Date Prepared:** June 30, 2006

**Predicate Devices** — The Grace Medical Adjustable Length and Fixed Length Partial and Total Ossicular Prostheses are substantially equivalent to the predicate devices listed below.

<table>
<thead>
<tr>
<th>Predicate Device</th>
<th>Manufacturer</th>
<th>510(k) Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>BELL Prostheses (Various Models)</td>
<td>Heinz Kurz GmbH</td>
<td>K972492</td>
</tr>
<tr>
<td>AERIAL Prostheses (Various Models)</td>
<td>Heinz Kurz GmbH</td>
<td>K972585</td>
</tr>
<tr>
<td>Length-Adjustable Partial (BELL Vario) and Total (AERIAL Vario) Ossicular Prostheses</td>
<td>Heinz Kurz GmbH</td>
<td>K990923</td>
</tr>
<tr>
<td>Smith &amp; Nephew PORP &amp; TORP</td>
<td>Gyrus ENT</td>
<td>K002737</td>
</tr>
<tr>
<td>Smith &amp; Nephew Off-Centered PORP</td>
<td>Gyrus ENT</td>
<td>K002464</td>
</tr>
<tr>
<td>Gyrus ENT Brackman Modified TORP</td>
<td>Gyrus ENT</td>
<td>?</td>
</tr>
</tbody>
</table>

**Intended Use** — The Grace Medical Adjustable Length and Fixed Length Partial & Total 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: Chronic middle ear disease, Otosclerosis, Congenital fixation of the stapes, Secondary surgical intervention to correct for a significant and persistent conductive hearing loss from prior otologic surgery, and surgically correctible injury to the middle ear from trauma.

Materials – The Grace Medical Adjustable Length and Fixed Length Partial & Total Ossicular Replacement Prostheses are manufactured from the same or similar materials as the predicate devices. The Grace Medical Adjustable-Length PORP’s and TORP’s contain a medical grade silicone sleeve fixed to the titanium shaft which allows for adjustment to length by the user.

Design Features – Various designs of Grace Medical Adjustable Length and Fixed Length Partial & Total Ossicular Replacement Prostheses are available to meet physician preference. The design features of the Grace Medical Adjustable Length and Fixed Length Partial & Total Ossicular Replacement raise no new safety or effectiveness issues.
Comparison Charts

<table>
<thead>
<tr>
<th>Intended Use</th>
<th>Grace Medical Adjustable Length and Fixed Length Prostheses (K972815)</th>
<th>Bell Prostheses Kurz (K972492)</th>
<th>Aerial Prostheses Kurz (K972585)</th>
<th>Vario Length-Adjustable Prostheses Kurz (K9903923)</th>
<th>Smith &amp; Nephew Porp &amp; Torp Gyrus ENT (K002737)</th>
<th>Smith &amp; Nephew Offset-Centered Porp Gyrus ENT (K002464)</th>
<th>Gyrus ENT Brackman Modified Torp Gyrus ENT (KXXXXX)</th>
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</thead>
<tbody>
<tr>
<td>Head Material(s)</td>
<td>Titanium (Titanium Alloy)</td>
<td>Titanium (Titanium Alloy)</td>
<td>Titanium</td>
<td>Titanium (Titanium Alloy)</td>
<td>Titanium (Titanium Alloy)</td>
<td>Hydroxylapatite</td>
<td>Plasti-pore</td>
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<tr>
<td></td>
<td>Hydroxylapatite (HA)</td>
<td>Hydroxylapatite</td>
<td></td>
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<tr>
<td></td>
<td>HA-Coated Ti</td>
<td>OtoSil (Silicone w/BaSO₄)</td>
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<tr>
<td></td>
<td>Stainless Steel</td>
<td>Polyethylene</td>
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<tr>
<td></td>
<td>Silicone</td>
<td>Stainless Steel</td>
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<td></td>
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<tr>
<td></td>
<td></td>
<td>Silicone</td>
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<tr>
<td>Shaft Material(s)</td>
<td>Titanium (Titanium Alloy)</td>
<td>Titanium (Titanium Alloy)</td>
<td>Titanium</td>
<td>Titanium (Titanium Alloy)</td>
<td>Titanium (Titanium Alloy)</td>
<td>Titanium (Titanium Alloy)</td>
<td>Plasti-pore w/wire</td>
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<tr>
<td></td>
<td>Ti w/Silicone Sleeve</td>
<td>Polyethylene</td>
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<td>Silicone</td>
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<tr>
<td></td>
<td>Polyethylene</td>
<td>Silicone</td>
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<tr>
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<td>Silicone</td>
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<tr>
<td>Head Shape</td>
<td>Circular</td>
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<td>Circular</td>
<td>Circular</td>
<td>Circular</td>
<td>Oval</td>
<td>Round</td>
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<tr>
<td></td>
<td>Semi-circular</td>
<td>Trapezoidal</td>
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<td>Oval</td>
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<tr>
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<td>Oblong</td>
<td>Notched</td>
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<tr>
<td>Functional Length (mm)</td>
<td>Fixed Sizes from 0.5 to 9.0</td>
<td>4.0 to 8.0</td>
<td>1.75 to 4.50</td>
<td>3.0 to 7.0</td>
<td>Adjustable model - Trimmed to length Intraoperatively</td>
<td>2.0 to 9.0</td>
<td>Unknown</td>
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<tr>
<td></td>
<td>Adjustable model - Trimmed to length Intraoperatively</td>
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<td></td>
<td></td>
<td></td>
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<td>8mm Trimmable</td>
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<tr>
<td>How Supplied</td>
<td>Sterile</td>
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<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
</tr>
</tbody>
</table>

Differences between the Grace Medical Modified Partial Ossicular Replacement Prostheses and the predicate devices should not raise new issues regarding safety or effectiveness.
Grace Medical, Inc.
c/o Mr. Jeff Cobb
8500 Wolf Lake Dr., Suite 110
Memphis, TN 38133

Re: K061853
Trade/Device Name: Grace Medical Adjustable and Fixed Length Partial & Total Ossicular Replacement Prostheses
Regulation Number: 21 CFR 874.3450
Regulation Name: Partial Ossicular Replacement Prostheses; Total Ossicular Replacement Prostheses
Regulatory Class: II
Product Code: ETB; ETA
Dated: June 30, 2006
Received: July 18, 2006

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 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" (21 CFR 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](http://www.fda.gov/cdrh/industry/support/index.html).

Sincerely yours,

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
Device Name:

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a) Indications for Use

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(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.