

K080070

**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**  
**K-Helix Partial Ossicular Replacement Prostheses**

**APR 17 2008**

Trade Name: The family of K-Helix Partial Ossicular Replacement Prostheses consists of:

- K-Helix Piston
- K-Helix PORP

Common Name: Partial Ossicular Replacement Prostheses  
Classification Name: Partial Ossicular Replacement Prostheses (CFR 21 § 874.3450)

Official Contact: Jeff Cobb  
Vice President of Regulatory Affairs & Quality  
Grace Medical, Inc.  
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Memphis, TN 38133  
Telephone: (901) 380-7000  
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Date Prepared: January 8, 2008

Predicate Devices

- 1) SMart ISJ Prosthesis manufactured by Gyrus ENT LLC and cleared via 510(k) No. K033554.
- 2) SMart Piston manufactured by Gyrus ENT LLC and cleared via 510(k) No. K003214.
- 3) Angular Prosthesis (Plester) manufactured by Heinz Kurz GmbH Medizintechnik and cleared via 510(k) No. K972492.
- 4) CliP Piston MVP manufactured by Heinz Kurz GmbH Medizintechnik and cleared via 510(k) No. K042503.

Intended Use – The Grace Medical Partial 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.

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

- (i) Nitinol (ASTM F2063-05)
- (ii) Unalloyed titanium (ASTM F67)
- (iii) Titanium alloy (ASTM F136)

Comparison Charts

K-HELIX PORP

	K-Helix PORP (Grace Medical, Inc.)	SMart ISJ (Gyrus)	SMart Piston (Gyrus)	Angular Prosthesis (Kurz)
Intended 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.	Same	Same	Same
Material(s)	Nitinol and/or Titanium	Nitinol	Nitinol Fluoroplastic	Titanium
Method of Attachment	Manual or Heat Crimp-Assist	Manual or Heat Crimp-Assist	Manual or Heat Crimp-Assist	Manual
Lengths	3.0mm to 18.0mm	n/a	3.0mm to 6.0mm	4.25mm to 4.75mm
How Supplied	Sterile	Sterile	Sterile	Sterile

K-HELIX PISTON

	K-Helix PISTON (Grace Medical, Inc.)	SMart ISJ (Gyrus)	SMart Piston (Gyrus)	Angular Piston (Kurz)
Intended 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.	Same	Same	Same
Material(s)	Nitinol and/or Titanium	Nitinol	Nitinol Fluoroplastic	Titanium
Lengths	3.0mm to 18.0mm	n/a	3.0mm to 6.0mm	4.25mm to 4.75mm
How Supplied	Sterile	Sterile	Sterile	Sterile

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



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**APR 17 2008**

Grace Medical  
c/o Jeff Cobb  
VP Regulatory Affairs and Quality Assurance  
8500 Wolf Lake Drive  
Suite 110  
Memphis, TN 38133

Re: K080070

Trade/Device Name: K-Helix Piston and PORP  
Regulation Number: 21 CFR 874.3450  
Regulation Name: Partial Ossicular Replacement Prosthesis  
Regulatory Class: Class II  
Product Code: ETB  
Dated: March 19, 2008  
Received: March 21, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 and Ear, Nose  
and Throat Devices

Office of Device Evaluation

Center for Devices and  
Radiological Health

Enclosure

K08 0070

510(k) Number:

Device Name: K-Helix Partial Ossicular Replacement Prostheses

The family of K-Helix Partial Ossicular Replacement Prostheses consists of:

- K-Helix Piston
- K-Helix PORP

**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:

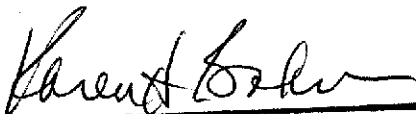
- (a) Chronic middle ear disease,
- (b) Otosclerosis,
- (c) Congenital fixation of the stapes,
- (d) Secondary surgical intervention to correct for a significant and persistent conductive hearing loss from prior otologic surgery, and
- (e) Surgically correctible injury to the middle ear from trauma.

(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)



(Division Sign-Off)  
Division of Ophthalmic Ear,  
Nose and Throat Devices

510(k) Number   K080070