

K 060518

**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**  
**Grace Medical Partial Ossicular Replacement Prostheses**

**JUN 28 2006**

Trade Name: Partial Ossicular Replacement Prostheses  
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  
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Date Prepared: February 16, 2006

Predicate Devices – The Grace Medical Stapes Prostheses are substantially equivalent to the current Partial Ossicular Replacement Prostheses marketed by Grace Medical, Inc. (K991934) and Partial Ossicular Replacement Prostheses marketed by Gyrus ENT LLC.

Intended Use – The Grace Medical Stapes Prostheses have the same primary intended use as the predicate devices, which are intended to be implanted for the functional reconstruction of segments of the ossicular chain and to facilitate 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 of Tubes – The Grace Medical Stapes Prostheses are manufactured from the same or similar materials as the predicate devices.

Design Features – Various designs of Stapes Prostheses are available to meet physician preference.

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Comparison Charts

GRACE MEDICAL CUP PISTONS VS. GRACE MEDICAL CUP PISTONS (K991394) VS. GYRUS ENT “RICHARDS” BUCKET HANDLE PROSTHESIS VS. GYRUS ENT SMART PISTON VS. GYRUS ENT HOUSE-TYPE WIRE LOOPS VS. GYRUS ENT SHEA CUP AND SHEA PLATINUM/FLUOROPLASTIC PISTONS

	<b>GRACE MEDICAL CUP PISTONS</b>	<b>GRACE MEDICAL CUP PISTON (K991394)</b>	<b>GYRUS ENT “RICHARDS” BUCKET HANDLE</b>	<b>GYRUS ENT SMART PISTON (K003214)</b>	<b>GYRUS ENT HOUSE-TYPE WIRE LOOPS</b>	<b>GYRUS ENT SHEA CUP AND SHEA PLATINUM / FLUROPLASTIC PISTONS</b>	<b>GYRUS ENT CAWTHORNE PISTONS</b>
<b>Intended Use</b>	Partial Reconstruction of the Ossicular Chain	Partial Reconstruction of the Ossicular Chain	Partial Reconstruction of the Ossicular Chain	Partial Reconstruction of the Ossicular Chain	Partial Reconstruction of the Ossicular Chain	Partial Reconstruction of the Ossicular Chain	Partial Reconstruction of the Ossicular Chain
<b>Material(s)</b>	Titanium Fluoroplastic Stainless Steel Platinum Tantalum Silicone Nitinol	Titanium Fluoroplastic Stainless Steel Platinum Tantalum	Stainless Steel Fluoroplastic	Fluoroplastic Nitinol	Stainless Steel	Fluoroplastic Platinum	Stainless Steel Fluoroplastic
<b>Shaft Diameter (mm)</b>	0.3 to 0.8	0.4 to 0.8	0.4 to 0.6	0.4 to 0.8		0.8	0.3
<b>Functional Length (mm)</b>	3.0 to 6.5	4.5 to 6.0	3.50 to 4.25	3.75 to 5.25	3.0 to 6.5	3.5 to 6	3.5 to 6.0
<b>How Supplied</b>	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile

GRACE MEDICAL STAPES PROSTHESES VS. GRACE MEDICAL STAPES PROSTHESES (K991394), GRACE MEDICAL WIRE LOOP PISTONS (K991394), GYRUS ENT SCHUKNECHT PISTONS, GYRUS ENT HOUSE-TYPE WIRE LOOPS AND GYRUS ENT “RICHARDS” PLATINUM FLUROPLASTIC PISTONS

	<b>GRACE MEDICAL STAPES PISTONS</b>	<b>GRACE MEDICAL STAPES PISTONS (K991394)</b>	<b>GRACE MEDICAL WIRE LOOP PISTONS (K991394)</b>	<b>GYRUS ENT SCHUKNECHT PISTONS</b>	<b>GYRUS ENT HOUSE-TYPE WIRE LOOPS</b>	<b>GYRUS ENT “RICHARDS” PLATINUM FLUROPLASTIC PISTONS</b>	<b>GYRUS ENT CAWTHORNE PISTONS</b>
<b>Intended Use</b>	Partial Reconstruction of the Ossicular Chain	Partial Reconstruction of the Ossicular Chain	Partial Reconstruction of the Ossicular Chain	Partial Reconstruction of the Ossicular Chain	Partial Reconstruction of the Ossicular Chain	Partial Reconstruction of the Ossicular Chain	Partial Reconstruction of the Ossicular Chain
<b>Material(s)</b>	Titanium Fluoroplastic Stainless Steel Platinum Tantalum	Titanium Fluoroplastic Stainless Steel Platinum Tantalum	Titanium Fluoroplastic Stainless Steel Platinum Tantalum	Stainless Steel Fluoroplastic	Stainless Steel	Platinum Fluoroplastic	Stainless Steel Fluoroplastic
<b>Shaft Diameter (mm)</b>	0.3 to 0.8	0.4 to 0.8		0.6 to 0.8		0.4 to 0.8	0.3
<b>Functional Length (mm)</b>	3.0 to 6.5	4.5 to 6.0	3.00 to 6.00	3.00 to 5.75	3.0 to 6.5	3.50 to 5.00	3.5 to 6.0
<b>How Supplied</b>	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile

GRACE MEDICAL FLUROPLASTIC PISTONS VS. GRACE MEDICAL FLUROPLASTIC PISTONS (K991394), GYRUS ENT CAWTHORNE PISTONS, GYRUS ENT HOUSE-TYPE WIRE LOOPS AND GYRUS ENT CAUSSE PISTONS

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	<b>GRACE MEDICAL FLUOROPLASTIC PISTONS</b>	<b>GRACE MEDICAL FLUOROPLASTIC PISTONS (K991394)</b>	<b>GYRUS ENT CAWTHORNE PISTONS</b>	<b>GYRUS ENT CAUSSE PISTONS</b>	<b>GYRUS ENT HOUSE-TYPE WIRE LOOPS</b>
<b>Intended Use</b>	Partial Reconstruction of the Ossicular Chain	Partial Reconstruction of the Ossicular Chain	Partial Reconstruction of the Ossicular Chain	Partial Reconstruction of the Ossicular Chain	Partial Reconstruction of the Ossicular Chain
<b>Material(s)</b>	Fluoroplastic	Fluoroplastic	Stainless Steel Fluoroplastic	Platinum Fluoroplastic	Stainless Steel
<b>Shaft Diameter (mm)</b>	0.3 to 0.8	0.4 to 0.8	0.3	0.4	
<b>Functional Length (mm)</b>	3.0 to 6.5	4.5 to 6.0	3.5 to 6.0	6.0	3.0 to 6.5
<b>Loop Dia (mm)</b>	0.4 to 0.8	0.6	0.8	0.6	
<b>How Supplied</b>	Sterile	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

**JUN 28 2006**

Grace Medical, Inc.  
c/o Mr. Jeff Cobb  
8500 Wolf Lake Dr., Suite 110  
Memphis, TN 38133

Re: K060518

Trade/Device Name: Partial Ossicular Replacement Prostheses  
Regulation Number: 21 CFR 874.3450  
Regulation Name: Partial Ossicular Replacement Prostheses  
Regulation Class: II  
Product Code: ETB  
Dated: February 24, 2006  
Received: June 1, 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" (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,



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

K060518

510(k) Number:

Device Name: Partial Ossicular Replacement Prostheses

1) Indications for Use

A partial 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.

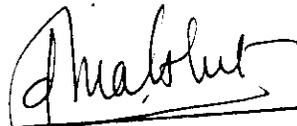
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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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