

K973672

DEC 18 1997

Summary of Safety and Effectiveness

Encore Orthopedics, Inc.
9800 Metric Blvd.
Austin, TX 78758
(512) 834-6237

Trade Name: Foundation® Plasma Sprayed Metal-backed Patella

Common Name: Metal-backed Patella

Classification Name: patellofemoral polymer/metal/polymer semiconstrained cemented prostheses as Class II.

Description: The Foundation® Plasma Sprayed Metal-backed Patella has a “sombbrero” shaped plastic articulating surface and a metal baseplate. The baseplate has three smooth pegs for rotational stability. The plastic component is manufactured from UHMWPE that conforms to ASTM F648. The metal baseplate is fabricated from wrought Ti-6Al-4V (ASTM F136) and is plasma sprayed with commercially pure titanium to provide a roughened surface to enhance cement fixation.

Intended Use: The Foundation® Plasma Sprayed Metal-backed Patella is intended to be used as a cemented patellar surface replacement in treating patients who are candidates for primary total knee arthroplasty as a result of osteoarthritis, inflammatory arthritis, traumatic arthritis or rheumatoid arthritis with or without varus, valgus, or flexion deformities, or revision arthroplasty where bone loss is minimal. It is intended to aid the surgeon in relieving the patient of knee pain and restoring knee joint function.

Comparable Features to Predicate Device(s): The Foundation® Plasma Sprayed Metal-backed Patella is the very same device in regards to articulating geometry, assembly, and indications for usage as the Porous Coated Metal-backed patella approved in K932246. The only difference is the coating applied. The Foundation® Plasma Sprayed Metal-backed Patella is equivalent in design and indications to the Miller/Galante (Zimmer) and Natural-Knee (Sulzer Orthopedics) metal-backed patella (Exhibit VII). These devices were cleared for commercial distribution on 510(k)s K863805 and K873601, respectively. Similarities include, metal-backed baseplate with Ti-6Al-4V substrate, “sombbrero” shaped articulating surface and three fixation pegs.

Test Results: Testing on this device included axial pushout and shear fatigue tests of the baseplate/plastic assembly. Results indicate that the attachment mechanism is sufficient to withstand the expected *in-vivo* loads.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 18 1997

Ms. Debbie De Los Santos
Regulatory/Clinical Specialist
Encore Orthopedics, Inc.
9800 Metric Boulevard
Austin, Texas 78758

Re: K973672
Foundation® Plasma Sprayed
Metal-Backed Patella
Regulatory Class: II
Product Code: JWH
Dated: September 24, 1997
Received: September 26, 1997

Dear Ms. De Los Santos:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). This decision is based on this device being equivalent only to similar devices labeled and intended to be fixed within bone with acrylic "bone cement." You may, therefore, market your device subject to the general controls provisions of the Act and the following limitations:

1. This device may not be labeled or promoted for non-cemented use.
2. All labeling for this device, including package label and labeling included within the package, must prominently state that the device is intended for cemented use only.

3. Any non-cemented fixation of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulation under 21 CFR, Part 812. All users of the device for non-cemented fixation must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) to conduct the investigation.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

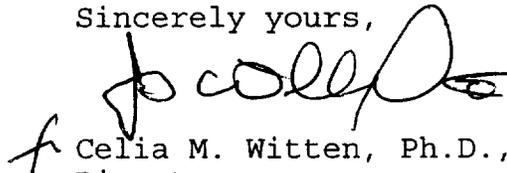
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be

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obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is fluid and cursive, with a large initial "C" and "W".

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K973672

Device Name: _____

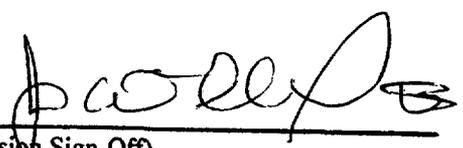
Indications For Use:

Foundation® Plasma Sprayed Metal-backed Patella
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(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 General Restorative Devices
510(k) Number K973672

Prescription Use X
(per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)_