

K974434

JAN 12 1998

510(k) Summary
Osteonics® Series 7000 Total Knee Anterior Femoral Blocks

Submission Information

Name and Address of the Sponsor: Osteonics Corporation
59 Route 17
Allendale, NJ 07401-1677

Contact Person: Terry Sheridan
Regulatory Affairs Specialist

Date of Summary Preparation: November 20, 1997

Device Identification

Proprietary Name: Osteonics® Series 7000 Total Knee Anterior Femoral Blocks

Common Name: Knee augmentation devices for total knee replacement femoral components

Classification Name and Reference: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
21 CFR §888.3530

Predicate Device Identification

The Osteonics® Series 7000 Total Knee Anterior Femoral Blocks are substantially equivalent to the following devices, which have previously been determined substantially equivalent by FDA:

- Osteonics® Series 7000 Distal Femoral Bone Augmentation Block and Posterior Femoral Bone Augmentation Block

Device Description

The Osteonics® Series 7000 Total Knee Anterior Femoral Blocks are characterized by the following design features.

- **Basic Anterior Femoral Shape:** The Osteonics® Series 7000 Total Knee Anterior Femoral Blocks conform to the outline of the proximal anterior aspect of the mating femoral component.
- **Size range:** The Osteonics® Series 7000 Total Knee Anterior Femoral Blocks are available in a range of sizes that correspond with mating femoral components.
- **Thickness:** The Osteonics® Series 7000 Total Knee Anterior Femoral Blocks are 3mm thick.

- Surface finish: The Osteonics® Series 7000 Total Knee Anterior Femoral Blocks feature an area roughened via a grit blast operation. The grit blasted surface provides a stronger bone cement/prosthesis interface than would a smooth or satin-finished surface.

Intended Use:

The Osteonics® Series 7000 Total Knee Anterior Femoral Blocks, because they are accessory components to an existing total knee replacement system, are subject to the general indications and contraindications of their mating knee femoral components, as follows:

Indications for Total Knee Replacement Components

- Painful, disabling joint disease of the knee resulting from degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.

Indications Specific to the Femoral Wedges

- Painful, disabling joint disease of the knee secondary to degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis, complicated by the presence of bone loss.
- Salvage of previous unsuccessful total knee replacement or other surgical procedure, accompanied by bone loss.

Assembly and Fixation Methods

Assembly

The Osteonics® Series 7000 Total Knee Anterior Femoral Blocks are intended for intraoperative assembly to mating knee femoral components. The operating room staff will use polymethyl methacrylate (PMMA) bone cement to affix a selected femoral block to its mating knee femoral component.

Fixation

The assembled block-to-femoral component construct is intended for cemented fixation to the prepared distal femur.

Statement of Technological Comparison:

The substantial equivalence of the Osteonics® Series 7000 Total Knee Anterior Femoral Blocks is supported by a comparison of the subject device to the above-cited predicate devices with regard to intended use, materials, and design.

Intended Use

Both the subject devices and the predicate femoral augmentation devices are intended to provide the surgeon with a prosthetic replacement for lost bone on the distal femur. The predicate femoral blocks are intended to address defects of the distal or posterior aspects of the distal femur, while the subject devices are intended to address defects of the posterior aspect of the distal femur. The subject and predicate knee augmentation components are intended for cemented assembly.

Materials

The subject devices are machined from Ti6Al4V alloy that complies with ASTM F-136, or cast from cobalt chromium alloy that complies with ASTM F-75. The predicate devices are also cast from cobalt chromium alloy. The cobalt chrome alloy version of the subject devices, then, is clearly substantially equivalent to predicate devices in terms of materials. The titanium alloy version of the subject devices differs from the predicate devices in terms of materials; however, this difference is not significant. Titanium alloy has a long history of use in orthopedics, and its use here as a non-articulating component raises no new questions of safety or efficacy.

Design

The subject devices, like the predicate devices, are modular augmentation blocks that come in a variety of sizes to match the intended mating knee femoral components. The subject and predicate devices are assembled to their mating femoral components via polymethyl methacrylate bone cement. The subject and predicate devices feature a roughened surface to enhance the device-to-cement interface.

Performance Data:

The Osteonics® Series 7000 Total Knee Anterior Femoral Blocks have been tested to ensure that the block-to-femoral component construct is strong enough to withstand anticipated in-vivo loading conditions. All specimens successfully endured 10 million cycles of physiologically relevant loading, with no signs of impending wedge/femoral component interface failure.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 1998

Ms. Terry Sheridan
Regulatory Affairs Specialist
Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K974434 --
Osteonics Series 7000 Total Knee
Anterior Femoral Blocks
Regulatory Class: II
Product Code: HRY
Dated: November 20, 1997
Received: November 24, 1997

Dear Ms. Sheridan:

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.

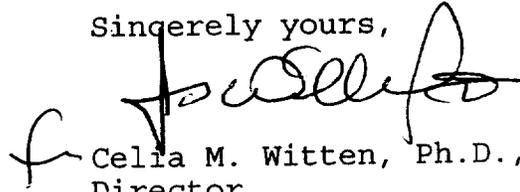
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the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

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): K974434

Device Name: Osteonics® Series 7000 Total Knee Anterior Femoral Blocks

Indications For Use:

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General Indications for Total Knee Replacement Components

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Polymethyl methacrylate (PMMA) bone cement will be used to affix a selected femoral block to its mating knee femoral component. The assembled block-to-femoral component construct is intended for cemented fixation to the prepared distal femur.

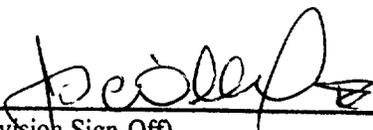
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____

(Optional Format 1-2-96)



 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K974434