

MAY -9 1997

**510(k) Premarket Notification  
Summary of Safety and Effectiveness  
for the  
Osteonics® Tibial Tray Screw Hole Plugs**

K970779

**Submission Information**

**Name and Address of the Sponsor  
of the 510(k) Submission:**

Osteonics Corporation  
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Allendale, NJ 07401-1677

**Contact Person:**

Kate Sutton  
Regulatory Affairs Specialist

**Date of Summary Preparation:**

March 3, 1997

**Device Identification**

**Proprietary Name:**

Osteonics® Tibial Tray  
Screw Hole Plugs

**Common Name:**

Tibial tray screw hole plugs

**Classification Name and Reference:**

Surgical mesh  
21 CFR §878.3300

**Predicate Device Identification**

The Osteonics® Tibial Tray Screw Hole Plugs are substantially equivalent to the following competitive and/or Osteonics devices, which have previously been determined substantially equivalent by FDA:

- Osteonics® Omnifit® Total Knee System Screw Hole Plugs
- Osteonics® Universal Cement Plug

**Device Description**

The Osteonics® Tibial Tray Screw Hole Plugs are small circular plugs which are manufactured from low density polyethylene (LDPE) and which are intended to occlude all tibial tray screw holes not occupied by bone screws. The Osteonics® Tibial Tray Screw Hole Plugs will be

factory-assembled into every tibial tray hole. Intraoperatively, the surgeon will remove the plugs from whichever screw holes will be filled with a bone screw.

The Osteonics® Tibial Tray Screw Hole Plugs, by occluding the tibial tray screw holes, will help prevent intrusion of bone cement onto the surface of the tibial tray.

**Intended Use:**

The Osteonics® Tibial Tray Screw Hole Plugs are intended to occlude the unused tibial screw holes of any Osteonics tibial tray component. The Osteonics® Tibial Tray Screw Hole Plugs will be used with bone cement. The Osteonics® Tibial Tray Screw Hole Plugs do not carry their own indications and contraindications, but-- as accessories to tibial tray components-- would be subject to all of the indications and contraindications of the associated tibial trays.

**Statement of Technological Comparison:**

The substantial equivalence of the subject devices to the predicate devices, in terms of design, materials, and intended use are discussed below.

***Design:***

The subject Osteonics® Tibial Tray Screw Hole Plugs and the UHMWPE screw hole plugs discussed in the predicate 510(k) are both circular disks intended to occlude unused screw holes. The subject devices are pre-assembled to their tibial trays at Osteonics, and may be removed by the surgeon intraoperatively.

***Materials***

The subject devices are made from low density polyethylene (LDPE). This material was chosen for its successful clinically demonstrated history of use, as well as its ability to be injection molded. The predicate cement plug is made from the same low density polyethylene as the subject device. Because the subject devices are non-load bearing, low density polyethylene is an appropriate material for this application.

***Intended Use:***

Both the subject Osteonics® Tibial Tray Screw Hole Plugs and the UHMWPE tibial tray screw hole plugs of the predicate Omnifit® Total Knee System are intended to occlude unused screw holes, thus preventing potential intrusion of bone cement.

The subject and predicate devices are intended for cemented applications only.

**Performance Data:**

Laboratory testing has been performed to evaluate the ability of the screw hole plugs to perform as intended under simulated physiological loading.