

K962132

AUG - 8 1996

**510(k) Premarket Notification  
Summary of Safety and Effectiveness  
for the  
Osteonics® Silkon™ Stainless Steel Cable System**

**Submission Information**

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

Osteonics Corporation  
59 Route 17  
Allendale, NJ 07401-1677

**Contact Person:**

Chuck Ryan  
Regulatory Affairs Team Leader

**Date of Summary Preparation:**

August 2, 1996

**Device Identification**

**Proprietary Name:**

Osteonics® Silkon™ Stainless Steel Cable System,  
which includes the following components:

- Osteonics® Silkon™ Stainless Steel Single Cable
- Osteonics® Silkon™ Stainless Steel Y Cable
- Osteonics® Silkon™ Stainless Steel Crimp

**Common Name:**

Cerclage Fixation Components

**Classification Name/Reference:**

Bone Fixation Cerclage  
21 CFR §888.3010

**Overview:**

The purpose of this 510(k) premarket notification is to address the addition of a sterile offering of this system.

**Predicate Device Identification:**

The components of the Osteonics® Silkon™ Stainless Steel Cable System are substantially

equivalent to those of the AME® Silkon™ Cable System, which was determined substantially equivalent by the U.S. Food and Drug Administration (FDA) via 510(k) Premarket Notification #K932687.

**Description of Devices:**

The Osteonics® Silkon™ Stainless Steel Cable System consists of two designs: a single, multi-strand, stainless steel cable with an individual monofilament wire leader and a stainless steel crimp; or one multi-strand, stainless steel, double cable with a monofilament Y-Leader and two stainless steel crimps.

**Intended Use:**

The Osteonics® Silkon™ Stainless Steel Cable System is indicated for cervical, thoracic and lumbar spinal trauma and/or the correction of scoliosis, kyphosis, and lordosis deformities. The Osteonics® Silkon™ Stainless Steel Cable System is also indicated for trochanteric reattachment, sternotomy indications, and trauma to the shoulder, elbow, hip, knee and ankle.

**Statement of Technological Comparison:**

The designs and stainless steel material characterizing the components of the Osteonics® Silkon™ Stainless Steel Cable System are identical to those of the predicate AME® Silkon™ Cable System.

**Performance Data:**

As the components of the Osteonics® Silkon™ Stainless Steel Cable System remain identical to those of the predicate AME® Silkon™ Cable System, which has been determined substantially equivalent via 510(k) Premarket Notification #K932687, no additional performance data is deemed necessary.