

K961725

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## 510(k) Summary

### OSCAR ORTHOSONICS SYSTEM FOR CEMENTED ARTHROPLASTY REVISION

Common/Classification Name: Sonic surgical instrument, 21 CFR 888.4580

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#### A. LEGALLY MARKETED PREDICATE DEVICES

The **OSCAR Orthosonics Ultrasonics Cement Removal System** is substantially equivalent to the Advanced Osseous Technologies System 10 Model 100 Surgical System (K900003), and is similar to the Cooper Lasersonics CUSA System 200M (K864983).

#### B. DEVICE DESCRIPTION

The **OSCAR Orthosonics Ultrasonic Cement Removal System** consists of a power module which generates the ultrasonic energy and provides overall control of the device, a handpiece, a set of cement removal probes, and an ultrasonic cleaning system for part of the reprocessing procedures for reuse of the probes. Three independent power modules are included in each device and these are mounted in a cart for ease of use.

#### C. INTENDED USE

The **OSCAR Orthosonics System for Cemented Arthroplasty Revision** is intended to assist in the removal of polymethylmethacrylate (PMMA) bone cement during arthroplasty revision.

#### D. TECHNOLOGICAL CHARACTERISTICS

The **OSCAR Orthosonics Ultrasonic Cement Removal System** has the same technological characteristics as the predicate device. The energy

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source is ultrasonic for both, and both have probes made of the titanium alloy Ti-6Al-4V.

#### **E. TESTING**

Orthosonics carried out testing to address the following issues:

- (1) temperature rise in bone during OSCAR procedures,
- (2) damage to bone from direct contact,
- (3) clinical experience,
- (4) reprocessing probes for use on the next patient,
- (5) electromagnetic compatibility,
- (6) electrical safety, and
- (7) validation of sterilization recommendations.

The results from all of these tests supported the safety and effectiveness of the Orthosonics OSCAR device and demonstrate that the Orthosonics OSCAR is substantially equivalent to the predicate devices.

#### **F. CONCLUSIONS**

The Orthosonics OSCAR device has the *same* intended use and target population as the predicate devices. Orthosonics has demonstrated through its performance tests on the OSCAR device and its comparison of OSCAR characteristics with those of the predicate device that the OSCAR device is substantially equivalent to the predicate device.