

DEC -9 1996

K962314

**510(k) Notification
Summary of Safety and Effectiveness
for the
Osteonics® Halifax® Plus Interlaminar Clamp 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:

June 10, 1996

Device Identification

Proprietary Name:

Osteonics® Halifax® Plus Interlaminar Clamp
System

Common Name:

Spinal Fixation Components

Classification Name/Reference:

Spinal Interlaminar Fixation Orthosis
21 CFR §888.3050

Predicate Device Identification:

The components of the Osteonics® Halifax® Plus Interlaminar Clamp System are identical and thus substantially equivalent to those of the AME® Halifax® Plus Interlaminar Clamp System, which was determined substantially equivalent by the U.S. Food and Drug Administration (FDA) via 510(k) Premarket Notification #K850039. (Note: In K850039, the AME® Halifax® Plus Interlaminar Clamp System was identified as the Halifax Spinal Clamp System, manufactured by AME's predecessor, Levtech, Inc.)

Description of Devices:

The Osteonics® Halifax® Plus Interlaminar Clamp System consists of three sizes (C1, 7mm, and

13mm) of threaded and matching unthreaded clamps made from titanium alloy. The system also features three lengths (10, 20, and 30 mm) of associated threaded screws made from commercially pure titanium and used to secure the aforementioned sets of matching threaded and unthreaded clamps.

Intended Use:

The subject devices are intended for single use and are indicated for patients with cervical sUBLUXATIONS and dislocations from C1-C7 to achieve posterior cervical stabilization.

Statement of Technological Comparison:

The designs, materials, intended use, and general manufacturing processes characterizing the components of the Osteonics® Halifax® Plus Interlaminar Clamp System are identical to those of the predicate AME® Halifax® Plus Interlaminar Clamp System.

Performance Data:

As the components of the Osteonics® Halifax® Plus Interlaminar Clamp System remain identical to those of the previously marketed, predicate AME® Halifax® Plus Interlaminar Clamp System, which has been determined substantially equivalent via 510(k) Premarket Notification #K850039, no additional performance data is deemed necessary.