



**AESCULAP**

K970549

**510(k) Summary of Safety and Effectiveness**  
*(in Accordance with SMDA of 1990)*

APR 30 1997

**Aesculap Titanium Alloy Bone Screws**

**Submitted by:**

Aesculap<sup>®</sup>, Inc.  
1000 Gateway Blvd.  
So. San Francisco, CA 94080

Contact: Victoria Mackinnon  
Phone: (415) 876-7000 x346  
FAX: (415) 589-3007

**Product Name**

Trade Name: Aesculap Titanium Alloy Bone Screws  
Common Name: Bone Screws  
Classification Name: Screw, Fixation, Bone

**Predicate Device**

The titanium alloy bone screws from Aesculap are identified as predicate devices.

**Device Description**

The subject of this premarket notification are 4.0mm titanium alloy (partially threaded and fully threaded) bone screws and associated manual orthopedic instruments designed to assist screw fixation.

**Intended Use**

The titanium alloy cortical bone screws presented in this submission are intended for long and small bone fracture fixation.

**Summary of Technological Characteristics**

Aesculap's Titanium Alloy Bone Screws represent no change in technological characteristics. There have been only minor modifications to product design.

**Performance Data**

No applicable performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, fatigue testing was performed on the titanium alloy screws; this information is detailed in the application. The Titanium Alloy Bone Screws will be manufactured in accordance with ISO and German Din Standards.



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**Substantial Equivalence**

Aesculap believes that the Titanium Alloy Bone Screws presented in this submission are substantially equivalent in design, function, and intended use to Aesculap's current line of bone screws and other existing legally marketed bone screws such as:

- AME Universal bone screw (subject to #K930107) and
- Ace Cortical bone screw (subject to #K912598).