

BioHorizons Implant Systems, Inc.  
510(k) Notification  
September 27, 1996

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## 510(k) Summary of Safety and Effectiveness

### Proprietary Name

AS 123 Prosthetic Instrument System

### Common Name

Screw installation and removal instrument

### Classification Name -

Prosthetic accessory

### Classification

Class III

### Official Contact

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### Device Description

The AS 123 Prosthetic Instrumentation System is a hand-operated instrument which facilitates the installation and removal of cover screws, temporary healing abutments, abutment screws and posts in dental implant procedures. All components are manufactured from surgical grade stainless steel.

The primary advantages of the AS 123 over other prosthetic instruments are as follows:

- advantage of vision and easy access to difficult-to-reach posterior regions
- tactile feedback of screw placement and removal
- control of torque associated with the operation

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The thumbwheel operation provides excellent tactile feedback in placement of prosthetic components. Driver bits are easily interchangeable with the AS 123 instrument. A t-handle attachment provides the necessary torque for installation of abutment screws.

Substantial Equivalence Information

The AS 123 Prosthetic Instrumentation System is substantially equivalent in all features which could affect safety or effectiveness to the Steri-Oss® "Prosthetic Instrumentation" and Implant Innovations, Inc. "Drivers and Placement Instruments"