

Indications for Use

510(k) Number (if known)

K160221

Device Name

Implance Dental Implant System

Implance Dental Abutment System

Indications for Use (Describe)

Implance Dental Implant System is indicated to use for surgical placement in the upper and lower jaw arches, to provide a root form means for single and multiple units' prosthetic appliance attachment to restore a patient's chewing function.

Implance Dental Implant can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading.

Immediate loading is restricted to the anterior mandible based on four splinted-interforminal placed implants.

Implance Dental Abutment System is used with a dental implant to provide support to prosthetic restorations such as crown, bridge and overdentures in partially or fully edentulous patients. Octa Abutment models that contain an abutment post height less than 4 mm are indicated only for multi-unit loading, such as bridge or overdenture.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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