DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*

K181266

Device Name
Implantswiss Dental Implant System, Implantswiss Dental Abutment System

Indications for Use *(Describe)*

Implantswiss 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. Implantswiss 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. Implantswiss 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 and Multi-Unit Abutment models that contain an abutment post height less than 4 mm are indicated only for multi-unit loading, such as a 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.

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