DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200867

Device Name
Implantswiss Dental Implant System and 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. All digitally designed Premill abutments for use with the Implantswiss Dental Abutment System are intended to be sent to a Novodent validated milling center for manufacture.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."