DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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See PRA Statement below.

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K151916

Device Name

TRI® Dental Implant System

Indications for Use *(Describe)*

The TRI® Dental Implant System is intended for placement in the bone of the maxillary or mandibular arch for the rehabilitation of edentulous and partially edentulous patients. TRI® Dental Implant System allows for one and two-stage surgical procedures. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading.
TRI Dental Implant System 6.5 mm implants are intended for delayed loading only.

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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