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)*

K190040

Device Name
Straumann® BLX Line Extension – New Abutments

Indications for Use *(Describe)*

Straumann BLX Healing Abutments for Bars and Bridges
Straumann Healing abutments are indicated to be placed in the patient's mouth at the end of the implant placement to protect the inner configuration of the implant and to form, maintain and stabilize the soft tissue during the healing process.
Healing abutments should be used only with suitable implant connections.
Healing components have a maximum duration of usage of 6 months.

Straumann BLX Temporary Abutments for Bar and Bridges
Prosthetic components directly or indirectly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations. Temporary components can be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase; they may not be placed into occlusion. Final abutments may be placed into occlusion when the implant is fully osseointegrated.
BLX Temporary Abutments have a maximum duration of usage of 180 days.

Straumann BLX Variobase Abutments for Bar and Bridges
Straumann® Variobase™ prosthetic components directly or indirectly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations. The prosthetic restoration (bridge or overdenture) can be cemented on the Straumann® Variobase™ prosthetic components. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and form the soft tissue during the healing phase. They may not be placed into occlusion. Final abutments and restorations may be placed into occlusion when the implant is fully osseointegrated.

Straumann BLX Variobase Abutments AS
The Straumann Variobase for Crown AS is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann Variobase for Crown AS are indicated for screw retained single tooth or cement-retained single tooth and bridge restorations. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and form the soft tissue during the healing phase. Temporary restorations are indicated to be placed out of occlusion. All digitally designed copings and/or crowns for use with the Straumann Variobase for Crown AS are intended to be sent to Straumann for manufacture at a validated milling center.

Straumann BLX Novaloc Abutments
The Straumann® Retentive System is indicated for the attachment of full or partial dentures on Straumann dental implants.

Straumann BLX CARES Abutments
The Straumann CARES Abutments are indicated for single tooth replacement and multiple tooth restorations.
The prosthetic restoration can be cemented or directly veneered/screw-retained.

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."