

DEC - 2 1997

KA73353

ATTACHMENT 7

510(k) Summary

ATTACHMENT 7 - 510(k) Summary

1. Applicant's Name and Address

Straumann USA (on behalf of Institut Straumann AG)

Reservoir Place

1601 Trapelo Road

Waltham, MA 02154

Telephone Number: 781-890-0001

Fax Number: 781-890-6464

Contact Person: Linda Jalbert, Director of Regulatory Affairs

2. Name of the Device

Trade Name: Bonding Base

Common Name: Orthodontic Bonding Base

Classification Name: Accessory to a dental implant (21 CFR 872.3640)

3. Legally Marketed Devices to which Equivalence is Claimed (Predicate Devices)

ITI Titanium Transverse Screw Coping (K943720)

ITI Octa Gold Coping (K894844)

3M Unitek orthodontic bands

4. Description of the Device

The orthodontic bonding base is screwed onto the ITI Octa system. The bonding base has an interior icositetrahedron (24 facets) which allows a positioning in the desired angulation (15° steps). The bonding surfaces are eccentric to the implant axis such that four different distances are available between implant axis and bonding surface. An orthodontic bracket is cemented to the orthodontic bonding base and it acts as an anchor for the application of orthodontic forces during treatment. After orthodontic use, the bonding base is removed and a standard prosthetic restoration placed on the implant.

5. Intended Use of the Device

The bonding base serves as an attachment surface for the cementing of orthodontic brackets.

6. Basis for Substantial Equivalence

The Orthodontic Bonding Base is substantially equivalent to 3M Unitek Orthodontic Bands, the ITI Titanium Transverse Screw Coping, the ITI Octa Gold Coping and the ITI Transverse Screw Gold Coping intended use, material and design as follows:

	Subject Device	Predicate Devices			
Features	Orthodontic Bonding Base	3M Unitek Orthodontic Bands	ITI Titanium Transverse Screw Coping	ITI Octa Gold Coping	ITI Transverse Screw Gold Coping
Intended Use	Serve as a base for orthodontic attachment	Serve as a base for orthodontic attachment	Serve as a base for prosthetic reconstruction	Serve as a base for prosthetic reconstruction	Serve as a base for prosthetic reconstruction
Materials	Titanium	Stainless Steel	Titanium	gold alloy	gold alloy
Design	<p>Heights of 5.5 mm and 6.5 mm.</p> <p>Width of 6.8 mm.</p> <p>Internal icositetrahedron (24 facets) for seating on Octabutment.</p> <p>Axial screw channel for attachment to abutment.</p>	<p>Tooth-shaped circular bands designed in a range of sizes to accommodate varying tooth anatomies and sizes.</p>	<p>Height of 8.0 mm.</p> <p>Internal icositetrahedron (24 facets) for seating on Octabutment.</p> <p>Transverse screw channel for attachment to abutment</p>	<p>Height of 4.0 mm.</p> <p>Internal octagon for seating on Octabutment.</p> <p>Axial screw channel for attachment to abutment.</p>	<p>Height of 5.2 mm.</p> <p>Internal icositetrahedron (24 facets) for seating on Octabutment.</p> <p>Transverse screw channel for attachment to abutment.</p>



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 2 1997

Ms. Linda Jalbert
Director, Regulatory Affairs
Straumann USA
Reservoir Place
1601 Trapelo Road
Waltham, Massachusetts 02154

Re: K973353
Trade Name: Bonding Base
Regulatory Class: III
Product Code: DZE
Dated: September 4, 1997
Received: September 5, 1997

Dear Ms. Jalbert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

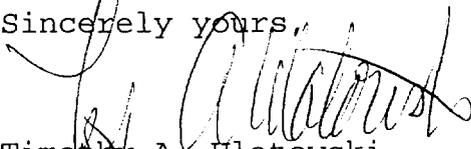
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): KA73353

Device Name: Bondin base

Indications For Use:

The bonding base is indicated for use with a standard ITI implant placed in the posterior oral cavity, to serve as a base for orthodontic attachment during orthodontic treatment.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runney

(Division Sign Off)
Division of Medical Control,
and Medical Devices

510(k) Number KA73353

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____