

APR 16

K990458

ATTACHMENT 9 - 510(k) Summary

1. **Applicant's Name and Address**

Straumann USA (on behalf of Institut Straumann AG)
Reservoir Place
1601 Trapelo Road
Waltham, MA 02451
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: Extraoral Implant
Common Name: Extra Oral Implant
Classification Name: Threaded Metallic Bone Fixation Fastener
(21 CFR 888.3040)

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

ITI SLA Dental Implant (K971578)
Nobel Biocare (K945154)
Leibinger Epitec Implant (K961719)
BUD Craniofacial Implant (K912521)

4. **Description of the Device**

The Extraoral implant is a solid, threaded, self-tapping implant made from CP titanium, Grade 4. It is available in insertion lengths ranging from 2.5 mm to 5.0 mm. It has the same rough surface as cleared Straumann endosseous dental implants. The transcutaneous abutments have a smooth machined surface to allow for the attachment of epithelial tissue.

5. **Intended Use of the Device**

The Straumann Extraoral implant is an endosseous implant intended for placement in the skull, mainly in the mastoid process, periorbital, and perinasal regions. Its purpose is to provide rigid retention for maxillofacial epitheses such as eye, ear and nose epitheses.

6. **Basis for Substantial Equivalence**

The Straumann Extraoral Implant is substantially equivalent to the Nobel Biocare Bone Anchored Craniofacial Prosthesis Anchoring System Implant, the Leibinger Epitec Implant, and the BUD Craniofacial Implant in intended use, material and

design. In addition, the Extraoral Implant is substantially equivalent to the ITI SLA Dental Implant in material and design.

The Extraoral implant has the same intended use as the Nobel Biocare Craniofacial Implant, the Bud Craniofacial Implant and the Leibinger Epitec Implant. Like these predicate implants, the Straumann Extraoral implant is intended to be used for the mechanical retention of a craniofacial prosthesis.

The Extraoral implant is composed of the same material and has the same surface as the ITI SLA dental implant. In addition, the design of the Extraoral implant is similar to the Nobel Biocare and the Bud implants. Like the ITI dental implant, the Extraoral implant has a rough SLA surface in contact with bone for osseointegration and a smooth titanium surface in contact with soft tissue. Like the Nobel Biocare and Bud implants, the Straumann Extraoral implants have a threaded self tapping implanted portion for anchorage in bone.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 16 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Linda Jalbert
Director of Regulatory Affairs
Straumann USA
Reservoir Place
1601 Trapelo Road
Waltham, Massachusetts 02451

Re: K990458
Trade Name: Straumann Extraoral Implant System
Regulatory Class: I
Product Code: KCZ
Dated: February 11, 1999
Received: February 12, 1999

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.

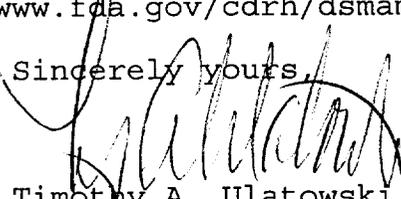
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Ms. Jalbert

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

Indications for Use Statement

Device Name:

Extraoral Implant

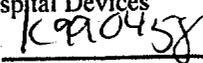
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(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number



Prescription Use
(Per 21 CFR 801.109)