K040539

MAR 1 8 2004

ATTACHMENT 6 - 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: 781-890-0791
Contact Person: John King
Regulatory Affairs

2. **Name of the Device**

Trade Name:	Elliptic Matrix
Common Name:	Endosseous dental implant
Classification Name:	Endosseous dental implant 21 CFR 872.3640

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

Gold Matrix (K894844)

4. **Description of the Device**

The Elliptic Matrix attaches to the retentive anchor by functioning like a spring when the four lamellae are activated. The titanium housing gives the matrix more support and retention for the denture.

5. **Intended Use of the Device**

The Elliptic Matrix is attached onto the retentive anchor abutment to provide support and retention for denture.

6. **Basis for Substantial Equivalence**

The subject device is substantially equivalent to previously cleared Gold Matrix. The intended use of the subject Elliptic Matrix is identical to the predicate Gold Matrix.

The subject device has an almost identical design as the predicate device. The labeling and instructions for use for both devices are similar.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 18 2004

Institut Straumann AG
C/O Mr. John King
Regulatory Affairs
Straumann USA
Reservoir Place
1601 Trapelo Road
Waltham, Massachusetts 02451

Re: K040539
Trade/Device Name: Elliptic Matrix
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: III
Product Code: NHA
Dated: March 1, 2004
Received: March 2, 2004

Dear Mr. King:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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.

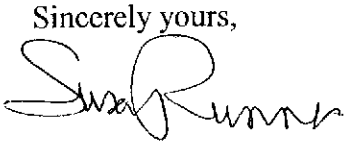
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K040539

510(k) Number (if known):

Device Name: Elliptic Matrix

Indications For Use:

The Elliptic Matrix is attached onto the Straumann Retentive Anchor abutment to provide support and retention for an overdenture.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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

510(k) Number: K040539