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K021355

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(K) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Brånemark Integration AB summary for the FIXTURE ORIGINAL.

SUBMITTER'S NAME:	Brånemark Integration AB
ADDRESS:	Lilla Bommen 1, SE-411 04 Göteborg, Sweden
CONTACT PERSON:	Rickard Brånemark
TELEPHONE NUMBER:	+46 (0)31 7601060
FAX NUMBER:	+46 (0)31 155260
DATE OF SUBMISSION:	April 22, 2002

1. Identification of device

Proprietary Name: Endosseous Implant

Common Name: FIXTURE ORIGINAL

Classification Status: Class III per regulations 872.3640

Product Codes: DZE

2. Equivalent devices

Brånemark Integration AB believes the FIXTURE ORIGINAL is substantially equivalent to Nobel Biocare AB standard fixture RP with a diameter of 3,75 mm.

3. Description of the Device

The FIXTURE ORIGINAL consists of 4 implants, diameter 3,75 mm, and length from 8,5 to 15 mm.

4. Intended use

The Brånemark Integration AB, FIXTURE ORIGINAL is intended for surgical placement into the bone of upper /lower jaw arches as a permanent anchorage for prosthetic devices and to restore chewing function.

5. Technological characteristics, comparison to predicate device.

Like the predicate devices, the FIXTURE ORIGINAL is intended to restore masticator function.

Comparison table

Characteristic	Nobel Biocare Standard Fixture	Brånemarsk Integration AB FIXTURE ORIGINAL
Indication for use	To be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patients chewing function.	The Brånemark Integration AB Fixture Original is intended for surgical placement into the bone of upper /lower jaw arches as a permanent anchorage for prosthetic devices and to restore chewing function.
Dimensions	Diameter 3,75 mm, Length 7-20 mm	Diameter 3,75 mm Length 8,5-15 mm
510(k)	K925765	No number yet

6. Discussion of performance testing.

Mechanical testing requested for Screw-type Endosseous Implants are described in the Guideline "Information Necessary for Pre Market Notification Submission for Screw-Type Endosseous Implants", dated December 9, 1996.

Brånemark Integration AB, FIXTURE ORIGINAL is substantially equivalent to Nobel Biocare Standard Fixture in material, dimensions, and intended use why we have come to the conclusion that further testing will not raise new issues of safety and efficacy.

Please see section 5, Part B Performance Testing.

7. Conclusion

Based on comparison to the predicate device, the Brånemark Integration AB, FIXTURE ORIGINAL, is substantially equivalent to previously cleared Nobel Biocare AB and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2002

Dr. Richard Branemark
President
Branemark Integration AB
Lilla Bommen 1, 11 tr
SE-411 04 Goteborg,
SWEDEN

Re: K021355
Trade/Device Name: Fixture Original
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: August 5, 2002
Received: August 7, 2002

Dear Mr. Branemark:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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

Enclosure

K021355

B. INDICATIONS FOR USE

510(k) Number_____

Device Name: Brånemark Integration AB, FIXTURE ORIGINAL.

Indications for Use:

The Brånemark Integration AB, FIXTURE ORIGINAL is intended for surgical placement into the bone of upper /lower jaw arches as a permanent anchorage for prosthetic devices and to restore chewing function.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use_____

(Per 21 CFR 801.109)

Susan Runner

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

510(k) Number: K021355