K040643

APR - 7 2004

SECTION I. 510(K) SUMMARY

Establishment Information	Brånemark Integration AB 1 Lilla Bommen Göteborg, Sweden, SE-411 04 Phone: +46 31 760 10 60 Fax: +46 31 15 52 60
Contact	Jan-Olof Djerf Quality Management & Regulatory Affairs, Manager Phone: +46 31 760 10 63
Proprietary Device Name	Brånemark Integration Dental Implant and Accessories
Classification Name	Endosseous Dental Implant (21 CFR 872.3640)
Device Classification	Class III
Statement	The information supporting claims of substantial equivalence, as defined under the Federal Food, Drug, and Cosmetic Act, respecting safety and effectiveness is summarized below.
Device Description	The Brånemark Integration implant products that are subject of this 510(k) are threaded, root-form implants fabricated from commercially pure titanium, and machined and are commercially available.
Intended Use	The BRÅNEMARK INTEGRATION products are intended for surgical placement into the bone of upper/lower jaw arches as a permanent anchorage for prosthetic devices and to restore chewing function.

Indications for use	The Brånemark Integration implants and accessories are subjected for one or two-stage surgical procedures, and either for cemented or screw retained prosthetic restorations. The implants are intended for immediate placement on a single tooth and/or multiple tooth applications recognizing sufficient bone stability (type I or II bone) and appropriate occlusal loading, to restore chewing and speech function. Multiple tooth applications may be connected with a bar.
Technological Characteristics	The technological characteristics of the Brånemark Integration implants and accessories remain substantially unchanged from the original Brånemark System® design . No design modifications were made that effect safety and effectiveness.
Performance Data	Clinical result show that expanded Indications for Use are as safe and effective as the original Indications for Use.
Conclusion	Based on the 510(k) summaries, 510(k) statements and the information provided in this submission, we conclude that the products are substantially equivalent to currently marketed devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 2004

Ms. Jan-Olof Djerf
Quality management & Regulatory Affairs, Manager
Branemark Integration A.B.
Lilla Bommen 1
SE-411 04 Gothenburg
SWEDEN

Re: K040643
Trade/Device Name: Brånemark Integration Endosseous Dental Implant
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: March 5, 2004
Received: March 11, 2004

Dear Ms. Djerf:

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) 594-5613. 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,

for, 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

SECTION 2 INDICATIONS FOR USE

510(k) Number K040643

Device Name: Brånemark Integration Endosseous Dental Implant

Indications for Use:

The Brånemark Integration AB, implants and accessories 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 X OR Over the Counter Use _____

(Per 21 CFR 801.109)

Robert S Betz DDS for D.S. Runner

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

510(k) Number: K040643