BBC

K052254

JUN - 1 2006

510(k) Summary of Safety and Effectiveness
(As Required by 21 C.F.R. §807.92)

Applicant:	Brainbase Corporation Yoneyama 2nd Bldg 6F, 22-13 Oi 1-chome, Shinagawa-ku Tokyo, Japan 140-0014
Contact Person:	Hiromi Shiojiri Phone 81 3 3778 0745 Fax 81 3 3778 4910 e-mail: mail@brain-base.com
Date of summary	July 26, 2005
Device name	Mytis Arrow Implant Systems
Common name	Endosseous Implant and Endosseous Dental Implant Abutment

Classification names	Regulation Number	Product Code
	21 CFR 872.3640	DZE (Implant)
	21 CFR 872.3630	HNA (Abutment)

Device Description The Mytis Arrow Implant system comprises various sets of root form endosseous dental implants and compatible implant abutment systems. Mytis Arrow Systems are designed for use in dental implant surgery and are intended to be used in a manor in which the implant integrates with the bone. The Mytis Arrow abutments include various abutments designed to enable the implant process from healing through final restoration. Mytis implants are for single and two-stage surgical procedures.

Predicate Device The device is substantially equivalent to other legally marketed devices in the United States including Branemark Implants (K022562 & K993595) and 3i Dental Implant Systems (K022113 & K022009).

Intended Use Mytis Implant Systems are intended for immediate placement in partially or fully edentulous mandibles and maxillae (type 1 or II bone), in support of single or multiple-unit restorations including; cement retained, screw retained, or over-denture restorations, and terminal or intermediate abutment support for fixed bridgework.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 1 2006

Brainbase Corporation
C/O Mr. Craig R. Bruns
Law Office of Craig Bruns
10 Montecito Drive
Danville, California 94526

Re: K052254
Trade/Device Name: Mytis Arrow XXXX
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: May 24, 2006
Received: May 30, 2006

Dear Mr. Bruns:

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

Indications for Use

510(k) Number: K052254

Device Name: Mytis Arrow XXXX

Indications For Use:

Mytis Arrow XXXX systems are intended for immediate placement in extraction or surgically prepared sites in partially or fully edentulous mandibles and maxillae (type 1 or II bone), in support of single or multiple-unit restorations including; cement retained, screw retained, or over-denture restorations, and terminal or intermediate abutment support for fixed bridgework.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K052251