K051576

SEP - 1 2005

510(k) Summary

Prepared May 24, 2005

TRADE NAME	AVANA Dental Implant System
GENERIC NAME	Endosseous Implant
CLASSIFICATION	Class II (21 CFR 872.3640)
SUBMITTED BY	EK SCIENCE REASEARCH INTL. CO. 9494 Silver Fern Pl. Rancho Cucamonga, CA 91730 tel. (909) 980-9933 fax. (909) 980-9951 email – ekscience@usa.com for Osstem Co., Ltd. #38-44, Guje 3-Dong Busan Republic of Korea 612-073
CONTACT	Mr. Ki Won Kim
PREDICATE DEVICE	Lifecore Stage –1 Single Stage RBM Dental Implant System, K-003226 Osstem Co. 3A Dental Implant System, K011879 Swissplus Dental Implant, K-002188
DEVICE DESCRIPTION	The Avana SS-II Implant is a threaded, root form endosseous implant comprised of an internal octa, one-stage 8° morse tapered device manufactured from commercially pure titanium. The implant's external threaded surfaces are roughened to facilitate tissue and bone integration. The implant's self-tapping feature may be used with or without pre-tapping the bone. System components for restorative purposes include: screw-on and cemented abutments, healing abutments, and angled abutments. Surgical accessories include drills, depth gages, drivers, torque wrenches, taps, reamers and fixture mount removal tool.

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INDICATIONS FOR USE	AVANA Dental Implant Systems are designed for use in dental implant surgery. A successfully osseointegrated implant will achieve a firm and direct connection between the living bone and the surface of the titanium fixture when surgically implanted under controlled conditions, as per well known clinical studies. They are intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.
TESTING	Biocompatibility of the AVANA Dental Implant System was verified in accordance with ISO 10993-1, Biological Evaluation of Medical Devices. Animal studies were conducted to determine the performance of the surface treatment. In-vitro performance tests were conducted to establish device durability as well as to characterize the implant surface treatment and purity. These studies included compression and fatigue tests as well as spectroscopic studies.
SUMMARY OF SUBSTANTIAL EQUIVALENCE	The AVANA Dental Implant System is substantially equivalent to the predicate devices in its construction, intended use and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Osstem Company Limited
C/O Albert Rego, Ph.D.
27001 La Paz, Suite 312
Mission Viejo, California 92691

Re: K051576
Trade/Device Name: AVANA Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: June 10, 2005
Received: June 14, 2005

Dear Dr. Rego:

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.

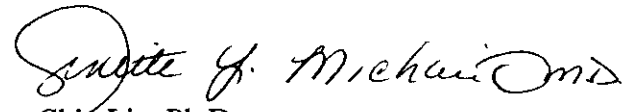
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 443-6597 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 Statement

510(k) Number (if known): K051576

Device Name:

AVANA Dental Implant System

Indications for Use:

AVANA Dental Implant Systems are designed for use in dental implant surgery. A successfully osseointegrated implant will achieve a firm and direct connection between the living bone and the surface of the titanium fixture when surgically implanted under controlled conditions, as per well known clinical studies. They are intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.

(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)

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

510(k) Number K051576