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Kens FineMedTech Sdn. Bhd. (769476-U)

(Formerly known as Bigeast Technologies Sdn. Bhd.)

510 (k) Summary of Safety and Effectiveness

JUN 18 2009

This summary regarding 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CRF 807.92.

Company	Kens FineMedTech Sdn.Bhd 19, Free Industrial Zone, Phase 4, Bayan Lepas, 11900 Penang. Malaysia Tel : (604)6161356 / 6161357 Fax : (604) 6161353
Contact Person	Leow Kok Hooi (General Manager)
Registration Number	769476-U
Prepared Date	01/05/2009
Proprietary Name	**KENS INTERNAL FIXATION SYSTEM**
Common Name	Bone Plate, Bone Screw , Pin and Wire
Reviewing Panel	Orthopedic
Classification Name	Class II , •CFR 888.3030 Single/Multiple Component Metallic Bone Fixation Appliances and Accessories Class II, •CFR 888.3040 Smooth or Threaded metallic Bone Fixation Fastener Class II, •CFR 888.3030 Appliance fixation, nail/blade/plate combination, multiple component
Device Code	HRS, HWC, KTT
Predicate devices:	INTAI Technology Corp., INTAI bone plates and bone screw system & INTAI DHS/DCS plate system (K063020)
Material:	

19, Hilir Sungai Keluang 2, Taman Perindustrian Bayan Lepas, Fasa IV, 11900 Penang, Malaysia

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The devices are manufactured from medical grade 316L stainless steel and Titanium that meets ASTM F138-08, ASTM F139-08, Titanium alloy ASTM F136-02a, and Pure Titanium ASTM F67-06.

Indication for Use:

The devices of **KENS INTERNAL FIXATION SYSTEM** are provided ***NON-STERILE.***

The Bone Plate, Bone Screw is intended for use in fixation of fractures to the various bones, including the clavicle, pelvis, scapula, calcaneus, long bone (humerus, ulna, radius, femur, tibia, and fibula), an small bone (metacarplas, metatarsals, and phalanges).

The DHS/DCS Plate System is intended for use in fixation of fractures to the proximal femur. The system is indicated for use in trochanteric, pertrochanteric, intertrochanteric, and basilar neck fractures.

Pin and Wire are indicated for use in fracture fixation, for healing of comminuted bone fragments, for osteotomies in the presence of adequate immobilization, as guide pins for insertion of other implants.

Description of Device:

The **KENS INTERNAL FIXATION SYSTEM** consists of ***NON-STERILE*** plate, screw, pins, wires and DHS/DCS plate systems. The plates are devices, which are fastened by screws to bone for the purpose of providing fixation. According functional differences, plates are gathered in four kinds: Dynamic Compression Plate (DCP), tubular, special and DHS/DCS. The shape of the plate is designed to an adaptation of the local bone anatomy and doesn't denote any particular function. **KENS** plates are divided as the following:

Product Name	Geometry Shape
DCP	Narrow, Broad, Broad Limited, Narrow Limited, Lengthening-Narrow, Lengthening Broad, Straight,
Tubular	Semi-tubular, one-third, quarter
Special	T-shaped, T-Buttress, T-Oblique, L-shaped, L-buttress, Cobra Head, Lateral tibial head, Condylar Buttress, Spoon, Reconstruction, Reconstruction-curved, Hook, H-shaped, W-shaped, Cloverleaf, Calcaneal, Y-Calcaneal, Adaptation, Compression, Multiple Fragment Plate, Condylar
DHS/DCS	Dynamic Hip Screw, Dynamic Condylar Screw

KENS screws & plates are grouped in 3 subsystems: mini fragment, small fragment and basic (also known as large fragment). The size range of plates are

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in thickness from 1.0 to 6.0mm, width from 3.8 to 17mm, length 17 to 370mm, and hole number from 2 to 22 holes. The size ranges of screw are in thread diameter from 1.5 to 7.0 mm, total length from 6 to 180mm. In which the screws are differentiated in 5 main kinds of: cortex, cancellous, malleolar, shaft and cannulated screws.

The DHS/ DCS plate system consists of DHS/DCS Plate, Lag Screw, DHS/DCS Compression Screw and 4.5mm Cortex Screw. The DHS Plates are available with short and standard barrel which length is 25mm and 38mm respectively. And the barrel angles are available in 95°, 135°, 140°, 145° and 150°. The self-tapping 4.5mm Cortex Screw can also be used to fix the DHS/DCS Plate to the femoral shaft. The DHS/DCS Screw is available in total length from 50 to 145 mm, thread length 22mm, shaft diameter 7.9mm, and outer diameter from 12.5 to 14mm.

The DHS/DCS Compression Screw with buttress thread, length 26mm and outer diameter 4.0mm, can be used to achieve fracture compression.

Pins and wires are divided into groups of:

- Kirschner wires are in length from 100 to 300mm and range in diameter is under 3.0mm and are available with trocar or diamond tip.
- Steinmann pin are in diameter 2.0~5.0mm and range in length from 125 to 300mm and are available with trocar or diamond tip.
- Schanz pins are supplied in diameter 1.25 ~6.0 and range in length from 80mm to 300mm.
- Knowles pins are with square and hexagonal drive, a break off length ranges from 63.5 to 152.4mm, and a thread diameter 4.0 & 4.8mm.

Substantial Equivalence:

The ***KENS*** Internal Fixation System has the same intended us, has similar performance characteristics, is manufactured from similar materials using similar processes, and is similar in design to the predicate devices of INTAI bone plates and bone screw system & INTAI DHS/DCS plate system (K063020).

Performance Data:

Instruction for Use and Labeling were given to understand the safety purposed all these instruction for use prior to clinical use and the results of laboratory (non-clinical) performance testing demonstrate that the devices are safe and effective.

19, Hilir Sungai Keluang 2, Taman Perindustrian Bayan Lepas, Fasa IV, 11900 Penang, Malaysia

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 2009

Kens FineMedTech Sdn.Bhd.
% Mr. Leow Kok Hooi
General Manager
19, Free Industrial Zone
Phase 4, Bayan Lepas,
11900 Penang, Malaysia

Re: K090786
Trade/Device Name: Kens Internal Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories.
Regulatory Class: Class II
Product Codes: HRS, KTT, HWC
Dated: February 21, 2009
Received: March 23, 2009

Dear Mr. Hooi:

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 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.

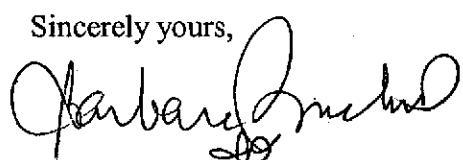
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,



Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090786

Device Name: KENS INTERNAL FIXATION SYSTEM

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K090786