



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 1 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Shimona Petroff
Vice President
Bregma International Trading Company Limited
214-111 Research Drive, Innovation Place
Saskatoon, Saskatchewan
Canada S7N 3R2

Re: K990351
Trade Name: Bone Screws
Regulatory Class: II
Product Code: HWC
K990353
Trade Name: Kirschner Wire and Steinman Pin
Regulatory Class: II
Product Codes: JDW and HTY
Dated: March 31, 1999
Received: March 31, 1999

Dear Ms. Petroff:

We have reviewed your Section 510(k) notifications of intent to market the devices referenced above and we have determined these devices are substantially equivalent (for the indications for use stated in the enclosures) to 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). You may, therefore, market the devices, 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.

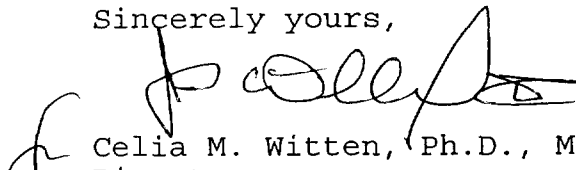
If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your devices in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Page 2 of 2510(k) Number (if known): K990351Device Name: Bone Screws

Indications For Use:

Bone screws are used to fix fractured long and short bones. They are also used to fasten bone plates. Bregma International manufactures three kinds of bone screws, each with its own intended use. Cortical bone screws are used to augment compact and hard bones (diaphyseal regions of the bones). Cancellous bone screws are used in the epiphyseal and metaphyseal regions of the bones which are largely soft and spongy. Cannulated bone screws, are used in situations where surgical wire is required to pass through the central axis of the screw, along which a hole has been drilled.

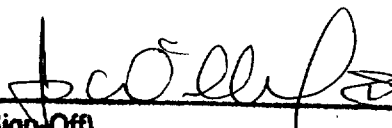
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Concurrence of CDRH, Office of Device Evaluation (ODE)Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)


(Division Sign Off)

Division of General Restorative Devices

510(k) Number

K990351