K970258

FERGUSON MEDICAL

916-342-4133
FAX: 916-343-4541

MAY 22 1997

15 January 1997

510(k) SUMMARY

The 510(k) summary information required by 21 CFR 807.92 is as follows:

A. Classification name: Screw, fixation, bone, or appliance, fixation, nail/plate/blade combination, multiple component.

Common/Usual name: Hip screw, hip pin, hip screw and plate, etc.

Proprietary name: Fixano D.S.S. (Double Sliding Screws) System For Osteosynthesis of Unstable Femoral Neck Fractures.

B. Substantial equivalence: Fixano D.S.S. (Double Sliding Screws) System (K954757), Synthes Dynamic Hip Screw (DHS) (K791619), Howmedica Omega Plus Compression Hip Screw System (K955306), and others.

C. Device description: The Fixano D.S.S. (Double Sliding Screws) System For Osteosynthesis of Unstable Femoral Neck Fractures is an implantable device to be used in orthopedic trauma procedures.

3407 Bay Avenue • Chico, California 95973 • USA

K970258

D. Intended use: The D.S.S. System For Osteosynthesis of Unstable Femoral Neck Fractures is intended for use in the fixation and osteosynthesis of unstable femoral neck fractures.

E. Technological characteristics: The D.S.S. System For Osteosynthesis of Unstable Femoral Neck Fractures is a hip screw mechanism that allows a natural, weight-bearing compression. The D.S.S. screws can be utilized alone, or in combination with a mini-plate, allowing flexibility of osteosynthesis in most configurations of unstable femoral neck fractures.

Submitted,
FERGUSON MEDICAL
FDA Establishment Registration Number 2937794

Frank Ferguson
Official Correspondent

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 1997

Mr. Frank Ferguson
Official Correspondent
Ferguson Medical
3407 Bay Avenue
Chico, California 95973

Re: K970257
Fixano Double Sliding Screws (D.D.S.)
with Intramedullary Nail
K970258
Fixano Double Sliding Screws (D.D.S.) and Mini-Plate
K970280
Fixano Double Sliding Screws (D.D.S.) and Sid Plate
Regulatory Class: II
Product Codes: HSB, HRS and HRS
Dated: April 15, 1997
Received: April 21, 1997

Dear Mr. Ferguson:

We have reviewed your Section 510(k) notification 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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,

for 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

10(k) Number (If known): K970258

Device Name: Fixano DSS (Double Sliding Screw) System For Osteosynthesis of Unstable Femoral Neck Fractures

Indications For Use:

This device is indicated for use in the fixation of unstable femoral neck fractures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K970258

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)