AUG 10 2007

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS: K071628
Stryker® Twist Drills

General Information

Proprietary Name:	Stryker® External Fixation System
Common Name:	External Fixation System
Proposed Regulatory Class:	Class II
Device Classification:	MQN (21 CFR 872.4760) External Mandibular Fixator and/or Distractor KTT (21 CFR 888.3030) Single/multiple component metallic bone fixation appliances and accessories.
Submitter:	Stryker® Craniomaxillofacial 750 Trade Centre Way Suite 200 Kalamazoo, MI 49002 877-534-2464 x 4250
Submitter's Registration #:	3005101424
Manufacturer's Registration #:	8010177
Contact Person:	Tennille Folk Regulatory Affairs Representative Phone: 877-534-2464 x 4250 Fax: 269-323-4215
Summary Preparation Date:	June 11, 2007

Intended Use

The Stryker® External Fixation System is intended to stabilize and provide treatment for fractures of the maxillofacial area, including severe open mandibular fractures, highly comminuted closed fractures, nonunions and delayed unions (especially associated with infection), fractures associated with infections, tumor resections, facial deformity corrections, gunshot wounds, pan facial fractures, burn maintenance, and bone grafting defects.

Substantial Equivalency Information

Stryker® considers the Stryker® External Fixation System are substantially equivalent to the already cleared Hoffman II Compact MRI External Fixation System (K053038), Hoffman II Compact External Fixation System (K961916, K971755 & K973321), Synthes Medium External Fixation System-MR Safe (K040258) and Synthes Sterile Mandible External Fixator (K062299).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Stryker® Craniomaxillofacial
% Ms. Tennillee Folk
Senior Regulatory Affairs Representative
750 Trade Centre Way
Suite 200
Kalamazoo, MI 49002

AUG 10 2007

Re: K071628
Trade/Device Name: Stryker® External Fixation System
Regulation Number: 21 CFR 872.4760
Regulation Name: External Mandibular Fixator and/or Distractor
Regulatory Class: II
Product Code: MQN, KTT
Dated: June 11, 2007
Received: June 14, 2007

Dear Ms. Folk:

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) 276-0120 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 toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Barbara Bucchip for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): K

Device Name: *Stryker® External Fixation System*

Indications for Use:

The Stryker® External Fixation System is intended to stabilize and provide treatment for fractures of the maxillofacial area, including severe open mandibular fractures, highly comminuted closed fractures, nonunions and delayed unions (especially associated with infection), fractures associated with infections, tumor resections, facial deformity corrections, gunshot wounds, pan facial fractures, burn maintenance, and bone grafting defects.

Prescription Use_____X_____ AND/OR Over-the-Counter Use_____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Posted November 13, 2003)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071628