K060654

510(k) Summary

Submitted by:	Delta Surgical Instruments, Inc. APR 28 2006 95 Schunnemunk Road Highland Mills, NY 10930 Dandenia Zabat Quality Assurance / Regulatory Manager 845-928-3760
Date prepared:	March 10, 2006
Classification Name:	Class II, 888.3040 - Smooth or Threaded Metallic Bone Fixation Fasteners
Common Name:	Bone Fixation Devices
Proprietary Name:	DSI Pins and Wires
Substantial Equivalence:	Comparative information presented supports substantial equivalence.
Description:	DSI Pins and Wires consist of various pins and wires for use in the fixation of bone fractures, bone reconstruction, or as a guide/aid for insertion of other medical devices. All DSI Pins and Wires included in this submission are manufactured of implant grade stainless steel. All DSI Pins and Wires included in this submission will be marketed non-sterile. Kirschner Wires, Steinmann Pins and Cerclage Wires are included in this submission.
Intended Use:	DSI Pins and Wires are non-sterile, single-use pins and wires intended to be used for the fixation of bone fractures, bone reconstruction, or as a guide/aid for the insertion of other medical devices.
Materials:	316 implant grade stainless steel

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 28 2006

Delta Surgical Instruments, Inc.
c/o Ms. Dandenia Zabat
Quality Assurance/Regulatory Manager
95 Schunnemunk Road
Highland Mills, New York 10930

Re: K060654
Trade/Device Name: DSI Pins and Wires
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HTY, JDW
Dated: March 10, 2006
Received: March 16, 2006

Dear Ms. Zabat:

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 its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Neil R.P. Ogden for

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

Enclosure

Indications for Use

510(k) Number (if known): K060654

Device Name: DSI Pins and Wires

Indications for Use:

DSI Pins and Wires are non-sterile, single-use pins and wires intended to be used for the fixation of bone fractures, bone reconstruction, or as a guide/aid for the insertion of other medical devices.

Prescription Use X **AND/OR** **Over-The-Counter Use** ____
(Part 21 CFR Subpart D) **(21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for

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

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