

COLORADO™ II Spinal System
Summary of Safety and Effectiveness
March 1999

MAY 1 0 2000

- I. Company: Sofamor Danek USA**
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133
- II. Proposed Proprietary Trade Name: COLORADO™ II Spinal System**
- III. Product Description**

The COLORADO™ II Spinal System consists of a variety of rods, hooks, screws, plates, staples, and other connecting components used to build a spinal construct. Instrumentation is also available to facilitate implantation of the device components.

COLORADO™ II Spinal System implant components are fabricated from stainless steel conforming to ASTM F138 or ISO 5832-1 or ISO 5832-9. Alternatively, the implant components may be manufactured from titanium alloy conforming to ASTM F-136 titanium alloy, or ISO 5832-3 and may be sold sterile or non-sterile. Stainless steel implants are not to be used with titanium alloy implants in a spinal construct.

IV. Indications

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the COLORADO™ II Spinal System Spinal System is indicated for one or more of the following: (1) degenerative spondylolisthesis with objective evidence of neurologic impairment, (2) fracture, (3) dislocation, (4) scoliosis, (5) kyphosis, (6) spinal tumor, and/or (7) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the COLORADO™ II Spinal System is also indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below);

and (4) who are having the device removed after the development of a solid fusion mass.

When used as a posterior, non-cervical, non-pedicle screw fixation system, the COLORADO™ II Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

When used as an anterolateral thoracic/lumbar system, the COLORADO™ II Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

V. Substantial Equivalence

The COLORADO™ II Spinal System is substantially equivalent to other legally marketed devices. Mechanical testing data were provided or referenced to demonstrate substantial equivalence.

**MAY 1 0 2000**Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Richard Treharne, Ph.D.
Vice President, Research and Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K991031
Trade Name: COLORADO II Spinal System (Ti Alloy version)
Regulatory Class: II
Product Code: MNH, MNI, KWP and KWQ
Dated: February 15, 2000
Received: February 16, 2000

Dear Dr. Treharne:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) 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 device, subject to the general control provisions of the Act. The general control 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 (Premarket Approval), 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 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 device 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 device as described in your 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.

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If you desire specific advice for your device 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 device, 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 at (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, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991031

Device Name: COLORADO™ II Spinal System

Indications for Use:

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Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)
(Optional 1-2-96)

OR

Over-the-counter Use _____

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K991031