FEB 8 2000

K994177

SutraTec, Inc.
8726 53rd Place, East
Bradenton, Florida 34202

510(K) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

The assigned 510(k) number is: _____.

Applicant:

SutraTec, Inc.
8726 53rd Place, East
Bradenton, Florida 34202
Mr. Joseph B. Gross, CEO
Tel: (941) 727- 2434

Contact:

Jonathan Green
Attorney-at-Law
Corporate Secretary, SutraTec
4740 Connecticut Avenue, N.W.
Suite 708
Washington D.C. 20008
Tel: (202) 966-3790

Date of 510(k) summary preparation: December 8, 1999

Trade name: SutraSilk

Common name: Suture, nonabsorbable, silk

Predicate devices:

SutraSilk nonabsorbable silk sutures manufactured by SutraTec are equivalent to Ethicon silk nonabsorbable sutures.

Device description:

SutraSilk silk suture is a nonabsorbable, sterile, surgical suture composed of an organic protein called fibroin. This protein is derived from the domesticated species Bombyx mori (B. mori) of the family Bombycidae. Those dyed black are dyed with Hematein (logwood) black and the logwood extract conforms with 21 CFR 73.1410 and does not exceed 1.0% (W/W) of suture.

This non-absorbable suture is composed of silk filaments that are braided or twisted in a suitable construction for the intended size to meet current USP specifications.

The suture may be uncoated or have a silicone coating, a paraffin wax coating, or a natural gum coating (Virgin silk). The sutures come with needles attached.

Intended use:

SutraSilk nonabsorbable silk sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

Performance tests to demonstrate substantial equivalency:

To establish the technical equivalency of SutraTec nonabsorbable braided silk surgical sutures with the predicate devices, tests according to methods presented in United States Pharmacopia (U.S.P.) were conducted for diameter, tensile strength and suture-needle attachment.

The test results shows that SutraTec devices tested meet USP standards and are technically equivalent to the predicate devices tested.

Jonathan Green, Corporate Secretary, SutraTec

Dec. 9, 1999
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 8 2000

SutraTec, Inc.
c/o Mr. Jonathan Green
4740 Connecticut Avenue, N.W., Suite 708
Washington, D.C. 20008

Re: K994177
Trade Name: SutraSilk
Regulatory Class: II
Product Code: GAP
Dated: December 9, 1999
Received: December 10, 1999

Dear Mr. Green:

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 to devices that were regulated as transitional devices and that have been reclassified into class II. Notice of this reclassification was published in the Federal Register on Tuesday, October 26, 1993 (Vol. 58, No. 205, Pages 57557 and 57558). A copy of this Federal Register can be obtained by calling the Division of Small Manufacturers Assistance (DSMA) at (800) 638-2041 or (301) 443-6597. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. The SutraSilk is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

2. This device may not be manufactured from any material other than multifilamentous fibers composed of fibroin, an organic protein that is derived from the domesticated species Bombyx mori (B. mori) of the family Bombycidae. In addition, you must maintain documentation at your premises regarding vendor certification for raw or semiprocessed source material, all manufacturing and quality control release procedures, and validation of sterilization procedures used in the manufacture of the SutraSilk. Any deviation of the source material or processing as described in this 510(k) notification requires submission of a new premarket notification and Food and Drug Administration (FDA) clearance prior to commercial distribution of the modified device.

The sale, distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801.109.

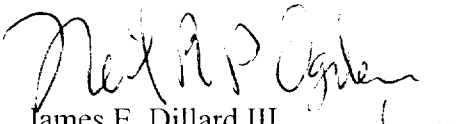
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibition against misbranding and adulteration.

Existing major regulations affecting your device can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) 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 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.

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) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4595. 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,



James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K994177

Indications for use

SutraSilk nonabsorbable silk sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

MRD for JTD

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994177

Prescription Use YES
(Per 21 CFR 801.109)