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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Per 21 CFR 807.92)

General Company Information

Name: Axya Medical, Inc.
Contact: Howard Schrayer
Regulatory Affairs Consultant

DEC - 4 2006

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Date Prepared October 18, 2006

General Device Information

Product Name: Tufflex™ polyester suture

Classification: "Nonabsorbable poly(ethylene terephthalate) surgical suture"
Product code: GAT - Class II
21 CFR 878.5000

Predicate Devices

Axya Medical, Inc.
AxyaFlex™ Polyester Suture
[510(k) Number K060165]

Smith & Nephew
DuraBraid™ Polyester Suture
[510(k) Number K040789]

Description

Tufflex™ polyester suture is a nonabsorbable, braided, sterile, surgical suture composed of poly(ethylene terephthalate co-isophthalate). It is prepared from fibers of high molecular weight, long-chain, linear polyesters having recurrent aromatic rings as an integral component. Tufflex™ sutures are braided for optimal handling properties.

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Intended Use (Indications)

Tufflex™ suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

Substantial Equivalence

This submission supports the position that the Tufflex™ polyester suture is substantially equivalent to a number of previously cleared devices, including the Axya Medical, Inc. AxyaFlex™ polyester suture and the Smith & Nephew DuraBraid™ Polyester Suture.

The 510(k) Notice contains summaries of studies that were conducted to evaluate the suture diameter and knot tensile strength as specified in the USP and in the FDA Guidance Document entitled "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA" (June 23, 2003).

The data presented demonstrate that the Tufflex™ polyester suture satisfied the USP requirements and was equivalent to the predicate materials.

The sutures are provided sterile. The suture material is sterilized using a process equivalent to the process used by the predicate suture manufacturers.

Conclusions

Axya Medical, Inc. believes that the information provided establishes that similar legally marketed sutures have been used for the same clinical applications as the indications for the Tufflex™ polyester suture. The material from which the Axya suture is fabricated and the suture coating have an established history of use in medical applications; and devices produced by Axya have been tested in accordance with applicable FDA guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Axya Medical, Inc.
% Mr. Howard L. Schrayer
100 Cummings Center, Suite 444C
Beverly, Massachusetts 01915

DEC - 4 2006

Re: K063194
Trade/Device Name: Tufflex™ Polyester Suture
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulation Class: II
Product Code: GAT
Dated: November 6, 2006
Received: November 8, 2006

Dear Mr. Schrayer:

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.

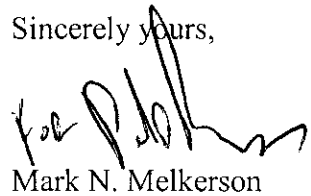
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

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INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Tufflex™ Polyester Suture

Indications For Use:

Tufflex™ Polyester Suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 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)

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

510(k) Number K063194