K060801

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Teleflex
MEDICAL

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2917 Weck Drive
RTP, NC 27709 USA
Phone: 919-544-8000
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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Dekna-lok™

A. Name, Address, Phone and Fax Number of Applicant

Teleflex Medical
2917 Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 919-361-8000
Fax: 919-361-4061

B. Contact Person

Kimberly Edgerton
Regulatory Affairs Specialist

C. Date Prepared

March 23, 2006

D. Device Name

Trade Name: Dekna-lok™

Common Name: Polyglycolytic Acid Surgical Suture

Classification Name: Absorbable poly(glycolide/l-lactide) surgical suture

Product Code: GAM

Regulation Number: 21 CFR 878.4493

Class: II

E. Device Description

Dekna-lok™ is Deknatel® Bondek® Plus Polyglycolic Acid Synthetic Absorbable Suture supplied with two integral acetal polymer buttressing components designed to spread the pressure of the suture across tissue.

F. Intended Use

Dekna-lok™ is indicated for use in general soft tissue approximation and/or ligation, but not for cardiovascular, neurological or ophthalmic procedures.

G. Substantial Equivalence

Dekna-lok™ is substantially equivalent to Teleflex Medical's Bondek® Plus Polyglycolic Acid Synthetic Absorbable Suture (K992088) with respect to functionality, design, and intended use and performance characteristics.

H. Summary of Testing

All materials used in the fabrication of Dekna-lok™ were evaluated through the recognized consensus standards as outlined in USP 28:2005 Absorbable Surgical Sutures and biological qualification safety tests as outlined in ISO 10993 Part 1 "Biological Evaluation of Medical Devices". Verification and Validation testing was performed according to the risk analysis. The design and materials were found to be acceptable for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2006

Teleflex Medical
% Ms. Kimberly Edgerton
Regulatory Affairs Specialist
2917 Weck Drive
Research Triangle Park, North Carolina 27709

Re: K060801
Trade/Device Name: Dekna-lok™
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly(glycolide/L-lactide) surgical suture
Regulatory Class: II
Product Code: GAM
Dated: March 23, 2006
Received: March 24, 2006

Dear Ms. Edgerton:

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.

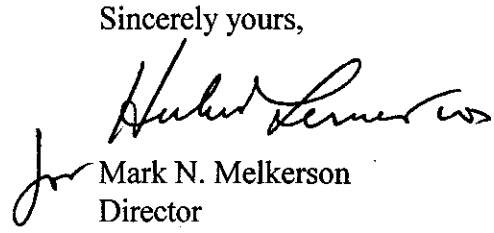
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

Teleflex MEDICAL

K060801

Teleflex Medical
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RTP, NC 27709 USA
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Indications for Use

510(k) Number (if known):

Device Name: Dekna-lok™

Indications For Use:

Dekna-lok™ is indicated for use in general soft tissue approximation and/or ligation, but not for cardiovascular, neurological or ophthalmic procedures.

Prescription Use ___X___ 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)

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

510(k) Number K060801