K073096 4/

510(k) Summary
Epitek Anchorage™ Closure Device

APPLICANT:

Epitek, Inc.
4801 W. 81st St., Suite 105
Bloomington, MN 55437 USA

FEB - 7 2008

Contact Person: Werner Hampl
Telephone: (952) 230-9886
e-mail: whampl@epitekinc.com
Date Prepared: October 31, 2007

DEVICE:

Proprietary Name:	Anchorage Closure Device
Common/Usual Name:	Suture with integral deployment device
Classification:	Class II; 21 CFR 878.5000; Nonabsorbable poly(ethylene terephthalate) surgical suture; Product Code: GAT

PREDICATE DEVICE:

The subject device is substantially equivalent (i.e., has the same intended use and technological characteristics) to the Genzyme Saph-Loop Ligating Loop (K022410) and SentreHeart LARIAT Loop Applicator (K060721).

DEVICE DESCRIPTION:

The Anchorage Closure Device is a one piece, single-use system comprised of components used to deliver and deploy a pre-tied suture in order to achieve soft tissue approximation and/or ligation.

INDICATIONS FOR USE:

The Anchorage Closure Device facilitates placement of a pre-tied ligature for use in surgical applications where soft tissue must be approximated and/or ligated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 7 2008

Epitek, Inc
% Mr. Werner Hampl
Vice President, Regulatory Affairs
And Quality Assurance
4801 West 81st Street, Suite 105
Bloomington, Minnesota 55437

Re: K073096
Trade/Device Name: Anchorage™ Closure Device
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly (ethylene terephthalate) surgical suture.
Regulatory Class: Class II
Product Code: GAT
Dated: January 17, 2008
Received: January 17, 2008

Dear Mr. Hampl:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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: Anchorage™ Closure Device

Indications for Use:

The Anchorage™ Closure Device facilitates placement of a pre-tied ligature for use in surgical applications where soft tissue must be approximated and/or ligated.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 K073096