510(k) Number K072470

510(k) SUMMARY

Trade Name:	BioElast™ 5-0 Suture NOV 1 6 2007
Sponsor:	ENTrigue Surgical, Inc. 3463 Magic Drive, Suite 320 San Antonio, Texas 78229 Telephone: 1-866-300-5010 Fax: 1-210-582-5811 Contact Person: Gabriele G. Niederauer, Ph.D.
Date of Summary:	August 31, 2007
Device Classification Name:	21 CFR §878.4494 Absorbable Poly(hydroxybutyrate) Surgical Suture
Classification:	According to Section 13 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards.
Predicate Devices:	Tepha, Inc., TephaFLEX® Absorbable Suture Ethicon, Inc., PDS*II
Device Description:	BioElast™ 5-0 Suture is a sterile, monofilament, absorbable surgical suture composed of poly-4-hydroxybutyrate. The BioElast™ 5-0 Sutures will be provided undyed at a 5-0 size.
Indications for Use:	BioElast™ 5-0 absorbable sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.
Safety and Performance:	Results of bench and in-vivo testing demonstrate that the BioElast™ 5-0 Suture is biocompatible and substantially equivalent in function to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 6 2007

ENTrigue Surgical, Inc.
% Gabriele G. Niederauer, PhD
VP, Research & Development
3463 Magic Drive, Suite 320
San Antonio, Texas 78229

Re: K072470
Trade/Device Name: BioElast™ 5-0 Suture
Regulation Number: 21 CFR 878.4494
Regulation Name: Suture, recombinant technology
Regulatory Class: II
Product Code: NWJ
Dated: August 13, 2007
Received: September 4, 2007

Dear Dr. Niederauer

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

K072470

Indications for Use Statement

510(k) Number (if known): K072470

Device Name: BioElast™ 5-0 Suture

Indications for Use:

BioElast™ 5-0 absorbable sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.

Prescription Use ☒	AND/OR	Over-The-Counter Use ☐
(Part 21 C.F.R. 801 Subpart D)		(21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K072470