JUL 15 2010

4. 510(k) Summary

General Information

Date Compile	April 30, 2010
Classificatior	21 CFR 878.5000, Nonabsorbable Polyethylene Terephthalate Surgica Suture Product code GAT, GDW
Trade Name	Modified NeoTract Anchor System
Common Name	Surgical Suture
Submitter	NeoTract, Inc. 4473 Willow Rd., Suite 100 Pleasanton, CA 94588 Tel: 415 609 9875 Fax: 925 401 0676 FDA Registration No.: 3005791775
Contact	Kevin MacDonald Vice President, Regulatory, Quality, Clinical Affairs

Intended Use

The Modified NeoTract Anchor System is intended for the approximation of tissue in open surgical procedures.

Predicate Devices

NeoTract Anchor System Manufactured by NeoTract, Inc.	K073651
Nonabsorbable Surgical Suture Manufactured by Genzyme Corporation	K021019
StomaphyX Delivery Device , Fasteners and Accessories Manufactured by EndoGastric Solutions, Inc.	K073644

Device Description

The Modified NeoTract Anchor System is used for the approximation of soft tissue in open surgical procedures. It consists of a single use delivery device that delivers the permanently implanted Suture Anchor. The delivery system is comprised of a polycarbonate handle and trigger assembly connected to a stainless steel shaft.

Materials

All materials used in the manufacture of the Modified NeoTract Anchor System are suitable for this use and are comparable to the predicate products.

Testing

In-vitro testing has been performed and all components, subassemblies, and/or full devices met the required specifications for the completed tests.

Summary of Substantial Equivalence

NeoTract, Inc. believes the Modified NeoTract Anchor System is substantially equivalent to the predicate products. The intended use, method of operation, methods of construction and materials used, are either identical or substantially equivalent to existing legally marketed predicate products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NeoTract, Inc.
% Mr. Kevin F. MacDonald
VP, Regulatory, Quality, Clinical Affairs
4473 Willow Road, Suite 100
Pleasanton, California 94588

JUL 15 2010

Re: K101252
Trade/Device Name: Modified NeoTract Anchor System
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: II
Product Code: GAT, GDW
Dated: April 30, 2010
Received: May 4, 2010

Dear Mr. MacDonald:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Peter D

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

Enclosure

K 10 12 52

3. Indications for Use Statement

510(k) Number (if known):	This application K 10 12 52
Device Name:	Modified NeoTract Anchor System
Indications for Use:	The Modified NeoTract Anchor System is intended for the approximation of tissue in open surgical procedures.

JUL 15 2010

Prescription Use _X_ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (Per 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)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101252