

K102028  
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#### 4. 510(k) Summary

##### General Information

Date Compiled July 16, 2010  
Classification 21 CFR 878.5000, Nonabsorbable Polyethylene Terephthalate  
Surgical Suture  
21 CFR 878.4750, Staple, implantable  
Product code GAT, GDW

Trade Name NeoTract Anchor System  
Common Name Surgical Suture

AUG 04 2010

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 TAS400 NeoTract Anchor System is intended for the approximation of tissue in open surgical procedures.

##### Predicate Devices

NeoTract Anchor System  
Manufactured by NeoTract, Inc.

K101252

##### Device Description

The TAS400 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 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 TAS400 NeoTract Anchor System is substantially equivalent to the predicate device. The intended use, method of operation, methods of construction and materials used, are either identical or substantially equivalent to existing legally marketed predicate products.



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, Clinical and Quality  
4473 Willow Road  
Pleasanton, California 94588

**AUG 04 2010**

Re: K102028  
Trade/Device Name: 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: July 16, 2010  
Received: July 20, 2010

Dear Mr. MacDoanld:

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

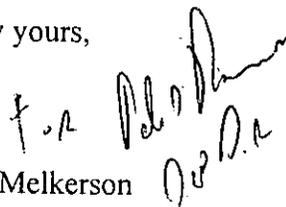
Page 2 - Mr. Kevin F. MacDonald

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" (21 CFR 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,



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

Enclosure

3. Indications for Use Statement

510(k) Number (if known):

This application

K102028

Device Name:

NeoTract Anchor System

Indications for Use:

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

AUG 04 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 Knepper M.D.  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K102028