DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 24, 2017

Nobles Medical Technologies II, Inc.
Mr. Jason Lyon
Director Regulatory Affairs
17074 Newhope St.
Fountain Valley, California 92708

Re: K162617
Trade/Device Name: Noblestitch El
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable Polypropylene Surgical Suture
Regulatory Class: Class II
Product Code: GAW
Dated: March 8, 2017
Received: March 15, 2017

Dear Mr. Lyon:

This letter corrects our letter of April 6, 2017.

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 and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

1. The safety and effectiveness of this device in percutaneous cardiac procedures such as closure of septal defects (e.g. patent foramen ovale, atrial septal defects and ventricular septal defects), closure of the left atrial appendage, and heart valve repair has not been established.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

William H. Maisel -S

William H. Maisel, M.D., M.P.H.
Director, Office of Device Evaluation (Acting)
Deputy Center Director for Science
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162617

Device Name
NobleStitch™ EL

Indications for Use *(Describe)*
The NobleStitch EL is indicated for use in the placement of sutures for soft tissue approximation in cardiovascular procedures. The NobleStitch EL is not intended for blind vascular closure.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) Summary

Per 21 CFR §807.92

Submitters Name and Address	Nobles Medical Technologies II, Inc. 17074 Newhope Street Fountain Valley, CA 92708	
Contact Name and Information	Jason K. Lyon Director Regulatory Affairs (Tel.) 714-427-6348 x225 (Fax) 714-427-6343	
Date Prepared	April 04, 2017	
Proprietary Name	NobleStitch EL Suturing Device	
Common Name	NobleStitch EL	
Product Code	GAW	
Classification of Device	Class II	
Predicate Device	Nobles Medical Technologies,Inc. NobleStitch EL, MR, and TA K113494 GAW 21 CFR 878.5010	Teleflex Medical, Inc. DEKLENE II, DEKLENE MAX II K153076 GAT 21 CFR 878.5000
Device Description	The NobleStitch EL device is a single-use surgical device, indicated for use in direct contact within the vascular and cardiovascular system. The NobleStitch EL device may be used by insertion through an access device (e.g. trocar, sheath or cannula), already in place following diagnostic or interventional procedures.	
Intended Use of Device	The NobleStitch EL is indicated for use in the placement of sutures for soft tissue approximation in cardiovascular procedures. The NobleStitch EL is not intended for blind vascular closure.	
Technological Characteristics	NobleStitch EL is composed of three components (primary, secondary, and Kwiknot). The primary and secondary handles each contain the operating mechanism, and a multi-lumen shaft containing a preloaded suture, a needle, a retractable arm, each of which is pre-loaded with one end of a suture. Upon placement, the Kwiknot is deployed to secure the suture.	
Non-Clinical Test Summary	Non-clinical testing was performed to demonstrate substantial equivalency to the predicate device, K113494. Bench test data consisted of: Functional Tests — Visual inspection and operation of the device. Performance tests — Actuation and verification of preloaded formed suture Clinical Simulation Tests — Actuated using a clinical simulation porcine model	
Conclusion	Based on safety and performance testing, technological characteristics and the indications for use. The NobleStitch EL is substantially equivalent to and as safe and effective as the predicate device (K113494).	