DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 18, 2015

Baylis Medical Company Incorporated
Ms. Meghal Khakhar
Director of Regulatory & Scientific Affairs
2645 Matheson Boulevard East
Mississauga, Ontario L4W 5S4
CANADA

Re: K151009
Trade/Device Name: Nexus™ Suture
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: Class II
Product Code: GAT
Dated: June 30, 2015
Received: July 6, 2015

Dear Ms. Khakhar:

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 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" (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 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 yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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)*
K151009

Device Name

Nexus™ Suture

Indications for Use *(Describe)*

Nexus™ Suture is indicated for use in approximation and/or ligation of soft tissues, including use of allograft tissue for orthopedic surgeries.

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.

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7. 510(k) Summary

Submitter Information

A. *Company Name*: Baylis Medical Company Inc.

B. *Company Address*: 2645 Matheson Blvd. East
Mississauga, Ontario L4W 5S4
Canada

C. *Company Phone*: (905) 602-4875

D. *Company Facsimile*: (905) 602-5671

E. *Contact Person*: Meghal Khakhar, Director of Regulatory & Scientific Affairs

F. *Summary Prepared on*: 13-Apr-2015

Device Identification

A. *Device Trade Name*: Nexus™ Suture

B. *Device Common Name*: Suture, nonabsorbable, synthetic, polyethylene

C. *Classification Name*: CFR 878.5000 - Nonabsorbable poly(ethylene terephthalate) surgical suture

D. *Product Code*: GAT

E. *Device Class*: Class II

Identification of Predicate Devices

The predicate devices are provided in Table 7.1.

Table 7.1: Predicate Devices

Predicate Device	**Manufacturer**	**510(k)**
Force Fiber Polyethylene Nonabsorbable Surgical Suture	Teleflex Medical	K033654
Force Fiber Blue Co-Braid Polyethylene Non-Absorbable Surgical Suture	Teleflex Medical	K040472

Indications for Use

Nexus™ Suture is indicated for use in approximation and/or ligation of soft tissues, including use of allograft tissue for orthopedic surgeries.

Device Description

Nexus Suture is a nonabsorbable, sterile, surgical suture provided in sizes 2-0, 0 and 2. It is composed of either undyed (white) ultra high molecular weight polyethylene (UHMWPE) or white UHMWPE braided with one or two strands of blue polypropylene to add color. The blue colorant is [phthalocyaninato(2-)] copper with a concentration not to exceed 0.5% by weight. It does not have a coating. Nexus Suture will be provided to the user in a variety of cut lengths without needles or on reels that facilitate suture handling.

Nexus Suture meets all USP requirements for non-absorbable surgical suture, except for oversized diameter.

Comparison to Predicate Devices

Nexus Suture and its predicate devices share the same intended use and fundamental scientific technology, including principles of operation and mechanism of action. The results of verification testing support the substantial equivalence determination to the predicate devices (Table 7.2).

Table 7.2: Comparison of Proposed and Predicate Devices

Characteristic	Proposed White Nexus Suture Compared to Predicate Teleflex Medical Suture (K033654)	Proposed White/Blue Nexus Suture Compared to Predicate Teleflex Medical Suture (K040472)
Intended Use	Identical	Identical
Indications for Use	Identical	Identical
Fundamental scientific technology	Identical	Identical
Operating principles	Identical	Identical
Mechanism of action	Identical	Identical
Technological aspects	Identical	Identical
Available Sizes	Similar*	Similar*

*The 2-0, 0 and 2 sizes are identical. Additional sizes available in the predicate are not applicable to the subject device.

Performance Testing

To demonstrate substantial equivalence of the Nexus Suture to the predicate devices, bench top testing was performed. The devices were subject to the following verification tests: biocompatibility, diameter testing and tensile strength testing.

Conclusions

Nexus Suture and its predicate devices share the same intended use and fundamental scientific technology, including principles of operation and mechanism of action.