DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 12, 2016

Teleflex Medical, Inc.
Ms. Natalie Hichak
Sr. Regulatory Affairs Specialist
3015 Carrington Mill Blvd.
Morrisville, North Carolina 27560

Re: K153089
Trade/Device Name: 'cottony' II Polyester Suture Tape, Pledgets
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT, DXZ
Dated: July 14, 2016
Received: July 15, 2016

Dear Ms. Hichak:

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" (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 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)*
K153089

Device Name
'cottony'™ II Polyester Tape

Indications for Use *(Describe)*
'cottony'™ II Polyester Suture Tape is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, orthopedic and neurological procedures.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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)*
K153089

Device Name
Pledgets

Indications for Use *(Describe)*
Deknatel Pledgets are indicated as sterile, single use, implantable devices for general suture reinforcement and suture buttressing.

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)

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Deknatel® 'cottony'™ II Tape and Pledgets

A. Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Inc.
3015 Carrington Mill Blvd
Morrisville, NC 27560

Phone: 919-433-8049
Fax: 919-433-4996

B. Contact Person

Natalie Hichak
Sr. Regulatory Affairs Specialist

C. Date Prepared

October 22, 2015

D. Product Classification

Product Code	GAT
Regulation Number	878.5000
Device Class	II
Classification Panel	Division of Surgical Devices (DSD) General Surgery Devices Branch One

Product Code	DXZ
C.F.R. Section	870.3470
Device Class	II
Classification Panel	Cardiovascular

E. Device Name

Trade Name	'cottony'™ II Tape
Common Name	Suture, Nonabsorbable, Synthetic, Polyethylene
Classification Name	Nonabsorbable poly(ethylene terephthalate) Surgical Suture

Available in the following product codes:

Product Code	Product Description
8-5037W	'cottony'™ II TAPE WHITE 3MM C-25 2N 18"
8-5044W	'cottony'™ II TAPE WHITE 3MM C-25 1N 18"
8-5062W	'cottony'™ II TAPE WHITE 3MM AC-25 2N 18
89-5037W	'cottony'™ II TAPE WHITE 3MM KC-25 2N 18
89-5044W	'cottony'™ II TAPE WHITE 3MM KC-25 1N 18"
X-3652	'cottony'™ II TAPE WHITE 5MM C-25 1N 12"
X-4142	'cottony'™ II TAPE WHITE 3MM KC-25 2N 30"
X-4323	'cottony'™ II TAPE WHITE 1MM HC-5 2N 20
X-5032	'cottony'™ II TAPE WHITE 2MM HC-5 2N 40"
X-5259	'cottony'™ II TAPE WHITE 1MM K-61 1N 20"
X-5750	'cottony'™ II TAPE WHITE 1MM K-61 1N 30"
X-5750M4	'cottony'™ II TAPE WHITE 1MM K-61 1N 30"X4
X-5798	'cottony'™ II TAPE WHITE 1MM HC-5 2N 30"
X-5819	'cottony'™ II TAPE WHITE 5MM KC-25 1N 40"
X-6081	'cottony'™ II TAPE WHITE 1MM HC-5 1N 30"
X-6464	'cottony'™ II TAPE WHITE 2MM 2 X 36”
X8-593	'cottony'™ II TAPE WHITE 3MM C-25 2N 12"

Trade Name Pledget
Common Name patch, pledget and intracardiac
Classification Name Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene

Available in the following product codes:

Product Code	Description
EK-705A	PLEDGET SOFT MEDIUM1/4"X1/8"X1/16"
EL-705A	PLEDGET SOFT LRG 3/8"X3/16"X1/16"
EQ-705	PLEDGET FIRM MED 1/4"X1/8"X1/16"
EW-705	PLEDGET FIRM SMALL 1/8"X1/8"X1/16"
EX-5145	PLEDGET SOFT 6"X5/16"X1/1
EX-6599	PLEDGET FIRM 5MMX3MM X1/16" X6
EZ-705	PLEDGET FIRM LARGE 3/8"X3/16"X1/16"
K-705	PLEDGET SOFT MEDIUM 1/4X1/8X1/16
L-705	PLEDGET SOFT LG 3/8X3/16X1/16
Q-705	PLEDGET FIRM MEDIUM 1/4"X1/8"X1/16"
W-705	PLEDGET SMALL FIRM 1/8X1/8X1/16

Product Code	Description
X-3523	PLEDGET SOFT 1/4X3/16X1/16PLEDGET
X-4016	PLEDGET SOFT 10MM X 7MM X 1.6MM
X-4340	PLED SOFT 1/4"X3/16"X1/16" X12
X-4420	PLEDGET SOFT 1"X1"X1/16"
X-4443	PLEDGET SOFT 6X1X1/16
X-4444	PLEDGET SOFT 3/4X1/2X1/16 X2
X-4460	PLEDGET SOFT 3/4"X5/16"X1/16" X6
X-4473	PLEDGET SOFT 1/2X1/4X1/16 X6
X-4475	PLEDGET SOFT 3/4"X3/8"X1/16" X6
X-4520	PLEDGET SOFT 3"X3"X1/16"
X-4527	PLEDGET SOFT 7/8X3/8X1/16 X2
X-4528	PLEDGET SOFT 3/4"X3/8"X1/16" X2
X-4543	PLEDGET SOFT 4"X5/16"X1/16" X2
X-4544	PLEDGET SOFT 1/2X5/16X1/16 X4
X-4550	PLEDGET SOFT 3/4X5/16X1/16 X2
X-4563	PLEDGET SOFT 5/8X3/8X1/16 X6
X-4564	PLEDGET SOFT 1/2"X5/16"X1/16" X6
X-4612	PLEDGET SOFT 5/8"X3/8"X1/16" X5
X-4615	PLEDGET SOFT 1/4"X3/16"X1/16" X5
X-4616	PLEDGET SOFT 3/4"X3/8"X1/16" X4
X-4625	PLEDGET SOFT 5/8"X5/16"X1/16" X6
X-4646	PLEDGET OVAL SOFT 6MMX4.5MMX1/16
X-4675	PLEDGET SOFT 8MMX8MMX1/16" X6
X-4714	PLEDGET SOFT 3/8"X3/8"X1/16" X2
X-4827	PLEDGET SOFT 5/16"X5/16"X1/16" X4
X-4832	PLEDGET SOFT 3/8"X3/8"X1/16" X8
X-4846	PLEDGET SOFT 7/8"X1/2"X1/16" X4
X-4874	PLEDGET SOFT 1/4"X1/4"X1/16" X12
X-5092	PLEDGET SOFT 1/4"X25/64"X1/16" X4
X-5145	PLEDGET SOFT 6"X5/16"X1/16" X2
X-5163	PLEDGET FIRM 3MMX5MMX1/16" X6
X-5437	PLEDGET SOFT 1/4X1/4X1/16
X-5468	PLEDGET SOFT LARGE 6"X6"
X-5508	PLEDGET FIRM 3/8"X1/8"X1/16”
X-5598	PLEDGET FIRM 1/8"X1/12"X1/16" X6

Product Code	Description
X-6633	PLEDGET SOFT OVAL 3/8"X5/16" 10PK
X-6658	PLEDGET SOFT 1/2"X1/4"X1/6 X4
X-6745	PLEDGET SOFT ROUND 6MM
X-6788	PLEDGET SOFT 3" X6"
X-6790	PLEDGET SOFT 6" X 1/2"
Z-705	PLEDGET FIRM LARGE 3/8X3/16X1/16

Additionally, the products listed above are available as part of suture kits in conjunction with the other suture materials cleared under K153076:

Product Code	Code	Qty	Description
V-1498A	**Surgical Closure Assortment**		
	XS-906	3	2 2 X 60” SILK black braided
	XS-935	1	0 12 X 30” SILK black braided
	XS-934	1	2-0 12 X 30” SILK black braided
	XS-933	1	3-0 12 X 30” SILK black braided
	XS-932	2	4-0 12 X 30” SILK black braided
	X-6464	2	2MM 2 X 36” ‘cottony’ II white braided
V-3777A	**Surgical Closure Assortment**		
	XRNS-537	10	0 1 X 18” SILK black braided
	7-717	3	2-0 4 X 30” TEVDEK II green braided
	C7-717	3	2-0 1 X 30” TEVDEK II green braided (Soft Pledget 3/8" x 3/16" x 1/16")
	XRN-5744	2	2-0 1 X 24” SILK black braided
	C7-5320	2	4-0 1 X 30” TEVDEK II green braided (Soft Pledget 3/8" x 3/16" x 1/16")
	S-7115B	2	5-0 1 X 24” SILK black braided
	XRN-5743	8	0 1 X 24” SILK black braided
	L-705	3	White Soft PLEDGET 3/8" x 3/16" x 1/16"
	D-7065A	2	4-0 1 X 36” DEKLENE II blue monofilament
	XCD-7065A	2	4-0 1 X 36” DEKLENE II blue monofilament (Soft Pledget 3/8" x 3/16" x 1/16")
	D-7061M2A	1	5-0 2 X 36” DEKLENE II blue monofilament
	RC-1424	1	2-0 12 X 18” SILK black braided
		1	4-0 12 X 18” SILK black braided
		1	4-0 12 X 18” SILK black braided
		1	4-0 12 X 28” SILK black braided

Product Code	Code	Qty	Description
		1	5 8 X 24” SILK black braided
		1	5 8 X 24” SILK black braided
		1	5 8 X 24” SILK black braided
		1	1 12 x 24” SILK black braided

F. Device Description

Deknatel Polyester Suture Tapes are nonabsorbable, sterile surgical sutures composed of Poly(ethylene terephthalate). They are prepared from fibers of high molecular weight, long-chain, linear polyesters having recurrent aromatic rings as an integral component. Deknatel Polyester suture tapes are provided braided, undyed (white) and dyed

Deknatel Pledgets are precut pieces from a sheet of polytetrafluoroethylene (PTFE) fabric used to spread the load the suture against host tissue.

G. Indications for Use and Contraindications

Trade Name	‘cottony’ II Tape
Indications for Use	‘cottony’ II Polyester Suture Tape is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, orthopedic and neurological procedures.
Contraindication	None known.

Trade Name	Pledgets
Indications for Use	Deknatel Pledgets are indicated as sterile, single use, implantable devices for general suture reinforcement and suture buttressing.
Contraindication	None known.

H. Substantial Equivalence

The proposed Deknatel 'cottony' II Tape and Pledgets are substantially equivalent the preamendment status of the devices and to the predicate devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
COTTONY’ II, “silky” II POLYDEK® & TEVDEK® II Polyester Nonabsorbable Surgical Suture	Genzyme Corp	K021019	June 18, 2002

I. Comparison To Predicate Devices

The Deknatel 'cottony' II Tape and Pledgets are a modification to the preamendment status of the devices. The modification is to add a stability claim of 5 years and to transfer the ownership from Genzyme to Teleflex Medical.

Additionally, the ‘cottony’ II Tape indications are being expanded to include the orthopedic indication as cleared in predicate K021019, COTTONY’ II, “silky” II POLYDEK® & TEVDEK® II Polyester Nonabsorbable Surgical Suture.

J. Materials

All patient contacting materials are in compliance with ISO10993-1.

K. Technological Characteristics

A comparison of the technological characteristics of the proposed Deknatel 'cottony' II Tape and Pledgets and the predicate has been performed. The results of this comparison demonstrate that the Deknatel 'cottony'™ II Tape and Pledgets are equivalent to the marketed predicate devices in performance characteristics.

L. Performance Data

Non-clinical testing has been performed in accordance with ISO11607-1:2006, *Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems* and *USP (United States Pharmacopeia) 36-NF 31 <871> Sutures- Needle Attachment, and <881>Tensile Strength* to demonstrate substantially equivalent to the predicate devices.

M. Conclusion

Based upon the comparative test results, the proposed Deknatel 'cottony' II Tape and Pledgets are substantially equivalent in performance to the predicate preamendment devices and devices cleared to market via 510(k) K021019.