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

July 12, 2016

Ethicon, Inc.
Ms. Enza Deserio
Regulatory Affairs Specialist
Route 22 West, P.O. Box 151
Somerville, New Jersey 08876

Re: K161726
Trade/Device Name: E-PACK™ Procedure Kit
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly(glycolide/L-lactide) surgical suture
Regulatory Class: Class II
Product Code: GAM, GAQ, FZP, GAN, GAW, FTL, LDF
Dated: June 20, 2016
Received: June 22, 2016

Dear Ms. Deserio:

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,

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)*
K161726

Device Name
E-PACK™ Procedure Kit

Indications for Use *(Describe)*
The modified E-PACK™ procedure kits are provided with the same package inserts with the same indication statements for each component of the kit, identical to the labeling provided with the individually marketed device.

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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ETHICON, INC.
a Johnson & Johnson company

510(k) Summary

Submitter: Ethicon, Inc. a Johnson & Johnson company
P.O. Box 151
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Somerville, NJ 08876-0151

Contact Person: Enza Deserio
Regulatory Affairs Specialist
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Date Prepared: June 20, 2016

Device Trade Name: E-PACK™ Procedure Kit

Device Common Name: Convenience Kit

Class: II

Classification Name: Absorbable poly (glycolide/l-lactide) surgical suture (21 CFR 878.4493)
Suture, Nonabsorbable, Steel, Monofilament And Multifilament, Sterile (21 CFR 878.4495)
Clip, Implantable (21 CFR 878.4300)
Suture, Absorbable, Synthetic (21 CFR 878.4830)
Suture, Nonabsorbable, Synthetic, Polypropylene (21 CFR 878.5010)
Mesh, Surgical, Polymeric (21 CFR 878.3300)
Electrode, Pacemaker, Temporary (21 CFR 870.3680)

Product Code: GAM, GAQ, FZP, GAN, GAW, FTL, LDF

Predicate Device Information:

Device	Company	Product Code	510(k) Number
E-PACK™	Ethicon, Inc.	GAM	K970317

Device Description:

Ethicon, Inc. E-PACK™s are considered convenience kits because two or more separate types of Ethicon finished devices are packaged together for the convenience of the user. Ethicon, Inc. certifies that all components within the E-PACK™ procedural kit are legally marketed devices manufactured by or for Ethicon, Inc. The classification of the kit is based on the highest classification of the devices that are provided in the kit. Ethicon, Inc. E-PACK™ Procedure Kits highest device classification is Class II.

The modified package will consist of individual finished devices, with or without their original primary package, that are placed into a plastic sleeve organizer that is subsequently placed into a blister tray with a Tyvek lid.

Indications For Use:

The modified E-PACK™ procedure kits are provided with the same package inserts with the same indication statements for each component of the kit, identical to the labeling provided with the individually marketed device.

Packaging:

The modified E-PACK™ packaging will consist of a rigid PETG Thermoform Blister with a Tyvek lid. The modified packaging will include a Plastic Organizer sleeve where the individual devices are placed. The Thermoform blister tray/Tyvek lid is placed in carton dispenser box. The Thermoform blister tray will come in three different sizes to accommodate the different sizes of E-PACK™ s (small, medium, and large). New products cleared through the 510(k) process will be available subsequently for inclusion in the E-PACK™. The 510(k) submissions for these products will state that they will be included in the appropriate E-PACK™.

Summary of Technological Characteristics and Performance Testing:

Ethicon, Inc. followed its internal procedures for Design Control and performed the following design control activities for E-PACK™ Procedure Kits:

i. Stability- Confirmed the stability of the E-PACK™ Procedure Kits and the individual products within the E-PACK™ Procedure Kits.
ii. Biocompatibility – Confirmed that E-PACK™ Procedure Kits meet the ISO 10993-7, Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals, requirements.

iii. Labeling – Confirmed the E-PACK™ Procedure Kits meet labeling requirements for convenience kits.
iv. Packaging/Transit Testing – Confirmed E-PACK™ Procedure Kit weight does not exceed the transit test worst case and the E-PACK™ components fit within the limits of the current packaging system. The proposed package configuration passed all transit testing requirements found in ISO 11607-1, Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems.
v. Sterilization- Confirmed that E-PACK™ Procedure Kit products can be sterilized with Ethylene Oxide and can be sterilized two times.

The safety and effectiveness of the modified E-PACK™ procedure kits and the substantial equivalence to the predicate device have been demonstrated via data collected during design verification. The results of these tests provide reasonable assurance that the modified device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing. The modified package configuration used for the proposed device meets the requirements ISO 14971:2007 Medical devices -- Application of risk management to medical devices and ISO 11607-1: 2006 Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems.

Summary of Substantial Equivalence:

The proposed device, Ethicon, Inc. E-PACK™, is substantially equivalent to the predicate, Ethicon, Inc. E-PACK™ in that they share:

- the same fundamental scientific technology,
- the same intended use,
- the same design,
- the same materials,
- similar packaging materials,
- the same labeling components,
- the same sterilization process (Ethylene Oxide),
- the same sterility assurance level (SAL) is 10-6 and
- the same shelf life.

In summary, the proposed device, Ethicon, Inc. E-PACK™, is substantially equivalent to the predicate Ethicon, Inc. E-PACK™, as further demonstrated in Table 2, Section 12: Comparison of Proposed and Predicate Devices.

Conclusion:

Based on the intended use, technological characteristics, safety and performance testing, the modified package configuration of the proposed E-PACK™ has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the predicate E-PACK™ (K970317).