February 8, 2018

Dura Tap, LLC
% Ms. Vikki O'Connor
Ambriel Associates, Inc.
Regulatory Affairs Consultant
411 Walnut St., Unit 9236
Green Cove Springs, Florida 32043

Re: K173335
Trade/Device Name: Gazelle PTFE Suture and Delivery Device
Regulation Number: 21 CFR 878.5035
Regulation Name: Nonabsorbable expanded polytetrafluoroethylene surgical suture
Regulatory Class: Class II
Product Code: NBY
Dated: November 17, 2017
Received: November 21, 2017

Dear Ms. O'Connor:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K173335

Device Name
Gazelle PTFE Suture and Delivery Device

Indications for Use *(Describe)*

Gazelle™ PTFE (polytetrafluroethylene) suture and Delivery Device is indicated for use in general soft tissue approximation and/or ligation, including; cardiovascular, dental, general surgical procedures and repair of the dura mater. Gazelle™PTFE sutures are not indicated for use in microsurgery, ophthalmic procedures, or peripheral neural tissues. Gazelle™ PTFE suture and Delivery Device is provided sterile as a single use 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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# 510(k) Summary: Gazelle PTFE (polytetrafluroethylene) Suture and Delivery Device

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular, 21 CFR Part 807.92, the following summary of information is provided:

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| Submitter: | Dura Tap LLC<br>Wayne, PA<br>USA |
| Contact Person | Ms. Vikki M. O'Connor<br>Regulatory Affairs Consultant<br>Phone: 1-207-214-8535<br>Email: vikki0730@yahoo.com |
| Date Prepared | January 12, 2017 |
| Trade Name | Gazelle PTFE Suture and Delivery Device |
| Proposed Class | Class II (special controls); General and Plastic Surgery |
| Classification Name and Number | Suture, Surgical, Nonabsorbable, Expanded, Polytetraflouroethylene, 878.5035 |
| Common Name | PTFE Nonabsorbable Surgical Sutures |
| Product Code | NBY |
| Predicate Device | Riverpoint Medical MONOTEX PTFE Suture – K140415 |
| Special Controls | FDA Guidance, "Class II Special Controls Guidance Document: Surgical Sutures, Guidance for Industry and FDA" was followed during the preparation of this submission. |
| Device Description | The Gazelle PTFE surgical sutures are monofilament surgical sutures composed from expanded polytetrafluoroethylene (ePTFE) material. They are available uncoated and undyed in USP sizes 5-0 and 6-0. |

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| | The sutures are attached to a standard stainless steel surgical needle.<br><br>The Gazelle Delivery Device is a Class I Manual Surgical Instrument that assists with suture placement. The PTFE suture is loaded into the Gazelle Delivery Device and is delivered to the desired location through the Gazelle device tip by pressing the actuation button on the Gazelle device handle. |
| Intended Use | The Gazelle PTFE (polytetrafluroethylene) Suture and Delivery Device are indicated for use in general soft tissue approximation and / or ligation, including cardiovascular, dental, general surgical procedures and repair of the dura mater. Gazelle PTFE Sutures are not indicated for use in microsurgery, ophthalmic procedures, or peripheral neural tissues. Gazelle PTFE Sutures are provided sterile as a single use device. |
| Summary of the Technological Characteristics | Gazelle PTFE Surgical Sutures are uncoated, undyed monofilament sutures composed from expanded polytetrafluoroethylene (ePTFE) material. The sutures are provided sterile for single use and meet all applicable USP requirements. |
| Performance Data | Gazelle PTFE Surgical Sutures meet the requirements specified in FDA's Class II Special Controls Guidance Document: Surgical Sutures, Guidance for Industry and FDA". In addition, the PTFE suture has passed performance testing, including mechanical testing in accordance to USP for nonabsorbable suture and biocompatibility testing of the suture material in accordance with ISO 10993-1. Packaging and sterilization validation and shelf life testing have been successfully performed. The Gazelle Delivery Device was tested for Button Push Force, Distal Tip / Shaft Pull |

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| | Force, Handle / Shaft Pull Force, Stylet / Button Pull Force and underwent surgeon evaluation. All testing has confirmed that the Gazelle PTFE Suture and Delivery System is substantially equivalent to it's predicate and will meet customer / user performance requirements. |
| Summary of Similarities and Differences | Both the subject and predicate are monofilament PTFE (polytetrafluroethylene) Nonabsorbable Surgical Sutures. Both are available in USP size 5-0 and 6-0 and are attached to stainless steel surgical needles. Both are uncoated and undyed. Both are provided sterilized for single use. Both meet USP requirements for Nonabsorbale Surgical Sutures, Tensile Strength and Needle Attachment. Riverpoint Surgical MONOTEX PTFE Sutures may not meet the USP requirement for diameter where Gazelle PTFE Sutures do meet the USP requirement for diameter. The only other difference is that the Gazelle PTFE suture is pre-loaded into the Gazelle Delivery Device. |
| Conclusion | Based on the indications for use, technological characteristics, required performance testing and comparison to the predicate device, Gazelle PTFE Suture and Delivery Device has been shown to be substantially equivalent to legally marketed predicate devices for its intended use. |