



February 15, 2018

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

Re: K173644

Trade/Device Name: Gazelle Polypropylene Suture and Delivery Device  
Regulation Number: 21 CFR 878.5010  
Regulation Name: Nonabsorbable Polypropylene Surgical Suture  
Regulatory Class: Class II  
Product Code: GAW  
Dated: November 22, 2017  
Received: November 27, 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](mailto: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

**Section 2A – Indications for Use**

**Indications for Use**

510(k) Number (if known)

K173644

Device Name

Gazelle™ Polypropylene Suture and Delivery Device

Indications for Use (Describe)

Gazelle™ Polypropylene Suture and Delivery Device is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurosurgical procedures. Gazelle™ Polypropylene 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 Polypropylene and Suture 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:

Submitter:	Dura Tap LLC Wayne, PA USA
Contact Person	Ms. Vikki M. O'Connor Regulatory Affairs Consultant Phone: 1-207-214-8535 Email: vikki0730@yahoo.com
Date Prepared	January 17, 2018
Trade Name	Gazelle Polypropylene Suture and Delivery Device
Proposed Class	Class II (special controls); General and Plastic Surgery
Classification Name and Number	Suture, Nonabsorbable, Synthetic, Polypropylene 878.5010
Common Name	Polypropylene Nonabsorbable Surgical Sutures
Product Code	GAW
Predicate Device	Riverpoint Medical RIVERPRO Suture – K100006
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 Polypropylene surgical sutures are sterile, nonabsorbable suture composed of an isotactic crystalline stereoisomer of polypropylene, a synthetic linear polyolefin. The pigmented suture is pigmented blue (with [Phthalocyaninato(2-)] copper, Color Index Number 74160) to enhance visibility. The sutures are attached to a standard stainless steel surgical needle.

	<p>The Gazelle Suture Delivery Device is a Class I Manual Surgical Instrument that assists with suture placement. The Polypropylene suture is loaded into the Gazelle Delivery Device and is delivered to the desired location through the tip of the Gazelle Delivery Device. A standard knot pusher may be included with the Gazelle Polypropylene Suture and Delivery Device.</p>
Intended Use	<p>The Gazelle™ Polypropylene Suture and Delivery Device is indicated for use in general soft tissue approximation and / or ligation, including cardiovascular, ophthalmic and neurosurgical procedures. Gazelle™ Polypropylene Suture and Delivery Device is provided sterile as a single use device.</p>
Summary of the Technological Characteristics	<p>Gazelle polypropylene Sutures are monofilament sutures composed of an isotactic crystalline stereoisomer of spropylene, a synthetic linear olefin. The pigmented suture is pigmented blue with [Phthalocyaninato(2-)] copper, Color Index Number 74160. The Gazelle Polypropylene Suture and Delivery Device is provided sterile for single use and meet all applicable USP requirements.</p>
Performance Data	<p>Gazelle Polypropylene Sutures meet the requirements specified in FDA's Class II Special Controls Guidance Document: Surgical Sutures, Guidance for Industry and FDA". In addition, the Gazelle Polypropylene 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</p>

	<p>Button Push Force, Distal Tip / Shaft Pull Force, Handle / Shaft Pull Force, Stylet / Button Pull Force and underwent surgeon evaluation. All testing has confirmed that the Gazelle Polypropylene Suture and Delivery Device is substantially equivalent and will meet customer / user performance requirements.</p>
<p>Summary of Similarities and Differences</p>	<p>Both the subject and predicate are monofilament Polypropylene Nonabsorbable Surgical Sutures. Both are available in USP size 5-0 and 6-0 and are attached to stainless steel surgical needles. Both are undyed or dyed with pigmented blue with [Phthalocyaninato(2-)] copper, Color Index Number 74160. Both are provided sterilized for single use. Both meet USP requirements for Nonabsorbable Surgical Sutures, Tensile Strength and Needle Attachment. The only other difference is that the Gazelle suture is pre-loaded into the delivery device.</p>
<p>Conclusion</p>	<p>Based on the indications for use, technological characteristics, required performance testing and comparison to the predicate device, Gazelle Polypropylene Suture and Delivery Device has been shown to be substantially equivalent to legally marketed predicate devices for its intended use.</p>