July 16, 2025

Q3 Medical USA, LLC (c/o Q3 Medical Devices Ltd.)
% John J. Smith
Partner
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, D.C., District of Columbia 20004

Re: K243412
Trade/Device Name: ARCHIMEDES Biodegradable Pancreatic Stent
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: Class II
Product Code: FGE
Dated: November 1, 2024
Received: June 27, 2025

Dear John J. Smith:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

STEPHANIE COLE -S

for Anthony C. Lee, Ph.D., M.B.A
Acting Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243412

Device Name

ARCHIMEDES Biodegradable Pancreatic Stent

Indications for Use *(Describe)*

The ARCHIMEDES biodegradable pancreatic stent is intended to drain pancreatic ducts in patients indicated for pancreatic duct stenting.

The ARCHIMEDES Biodegradable Pancreatic Stent is intended to be delivered through the working channel of a therapeutic endoscope using a guidewire with a maximum outer diameter of 0.035 inches and a pushing catheter of between 5 to 10 French.

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.

510(k) Summary

K243412

1. Submitter

Company Name:	Q3 Medical USA, LLC
Company Address:	1800 Camden Rd., Suite 107 Charlotte, NC 28203
Contact:	Eric K. Mangiardi, MSc. President and CEO (704) 712-1331 emangiardi@q3medical.com

Date Prepared: July 15, 2025

2. Device

Trade Name:	ARCHIMEDES™ Biodegradable Pancreatic Stent
Common Name:	Pancreatic Stent
Product Code:	FGE
Device Class:	Class II
Device Panel:	Gastroenterology / Urology
Classification Regulation:	21 CRF 876.5010, Biliary catheter and accessories

3. Predicate Device

Trade Name:	Advanix TM Pancreatic Stent and NaviFlex TM Rapid Exchange (RX) Pancreatic Delivery System and Pushers
Clearance number:	K133700
Common Name:	Stents, Drains, and Dilators for the Biliary Ducts
Product Code:	FGE
Device Class:	Class II
Device Panel:	Gastroenterology / Urology
Classification Regulation:	21 CRF 876.5010, Biliary catheter and accessories

4. Reference Device

Trade Name:	Microvasive Temporary Ureteral Drainage Stent
Clearance number:	K013784
Common Name:	Ureteral Stent, Indwelling Ureteral Catheter
Product Code:	FAD
Device Class:	Class II
Device Panel:	Gastroenterology / Urology
Classification Regulation:	21 CFR 876.4620 – Stent, Ureteral

5. Device Description and Technological Characteristics

The ARCHIMEDES™ Biodegradable Pancreatic Stent is a single use, sterile, biodegradable stent implant intended for use in the pancreatic duct. The device is intended to be delivered endoscopically through the working channel of a duodenoscope.

The ARCHIMEDES™ has a fluted cross-sectional profile and provides three drainage channels, two of which spiral in a double helical pattern down the length of the stent and one of which is the hollow inner lumen of the device tube. This unique design permits fluids to flow both around and through the stent. It has a curved form design to fit the natural curvature of the pancreatic duct, and contains flap and split-end features to minimize spontaneous migration of the stent while in situ. The tips of the stent are tapered to facilitate atraumatic insertion through the papilla. The stent is visible under fluoroscopy. The 8F and 10F stent design contains flaps on each end. The 6F stent design has a flap on one end and a split-end feature on the other end.

The stent is offered in outer diameters of 2.0mm (6F), 2.6mm (8F), or 3.4mm (10F), and in various lengths to accommodate variations in pancreatic anatomy across individuals (40, 60, 80, 100, 125, 150, 175, 200, and 225 mm). The ARCHIMEDES™ is designed to be an alternative to plastic stents that maintains the same clinical purpose. In particular, it is used in a manner similar to current FDA-cleared plastic pancreatic stents. The primary difference is that the ARCHIMEDES™ biodegrades in-situ rather than requiring an additional procedure for removal needed of plastic stents.

The Minimal Strength Retention (MSR) time for the material - i.e., the minimum amount of time for which the device retains at least 10% of an initial strength parameter and remains intact with no breaks is 12 days. Full-degradation or no stent presence is reached within <95 days.

6. Indications for Use

The ARCHIMEDES™ biodegradable pancreatic stent is intended to drain pancreatic ducts in patients indicated for pancreatic duct stenting.

The ARCHIMEDES™ Biodegradable Pancreatic Stent is intended to be delivered through the working channel of a therapeutic endoscope using a guidewire with a maximum outer diameter of 0.035 inches and a pushing catheter of between 5 to 10 French.

7. Comparison to the Predicate Device

Primary Predicate Device

The ARCHIMEDES™ Biodegradable pancreatic stent is substantially equivalent to the currently marketed Advanix™ Pancreatic Stent and NaviFlex™ RX Pancreatic Delivery System and NaviFlex Pushers (K133700) as follows: same intended use and principles of operations, same packaging and sterilization methods; and similar technological characteristics.

Reference Device

The Microvasive Temporary Ureteral Drainage Stent (K013784) is an appropriate reference device, as it has the same general principles of operation in facilitating short-term drainage of fluid and it is a biodegradable stent that was cleared on the basis of demonstrating substantial equivalence to a nonabsorbable stent predicate device.

The ARCHIMEDES fast-degrading pancreatic stent shares key technological characteristics with the proposed predicate device in that they are both implantable stents intended to drain pancreatic ducts. The stents are ofered in various lengths to accommodate diferent patients' anatomies.

The main technological diference between the ARCHIMEDES and the proposed predicate device is the stent material. The ARCHIMEDES stent is made of a bioresorbable polymer that degrades in the patient's body over time, and thus does not require removal. The Advanix stent is also made of a polymer, but it is not biodegradable, and therefore must be removed. However, this diference does not raise new questions of safety or efectiveness. The ARCHIMEDES stent operates in the same manner as existing non-biodegradable pancreatic stents for which the risks are well-understood and adequately mitigated through general and special controls.

Device Properties	**ARCHIMEDES Biodegradable Pancreatic Stent** **(Subject Device)**	**AdvaniX™ Pancreatic Stent and NaviFlexQm Rapid Exchange (RX) Pancreatic Delivery System and Pushers** **(Primary Predicate)** **K133700**	**Microvasive Temporary Ureteral Drainage Stent** **(Reference Device)** **K013784**
Intended Use/Indications for Use	The ARCHIMEDES biodegradable pancreatic stent is intended to drain pancreatic ducts in patients	The Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX)	The device is intended to facilitate the passage of

Device Properties	ARCHIMEDES Biodegradable Pancreatic Stent (Subject Device)	AdvaniX™ Pancreatic Stent and NaviFlexQm Rapid Exchange (RX) Pancreatic Delivery System and Pushers (Primary Predicate) K133700	Microvasive Temporary Ureteral Drainage Stent (Reference Device) K013784
	indicated for pancreatic duct stenting. The ARCHIMEDES Biodegradable Pancreatic Stent is intended to be delivered through the working channel of a therapeutic endoscope using a guidewire with a maximum outer diameter of 0.035 inches and a pushing catheter of between 5 to 10 French.	Pancreatic Delivery System and Pushers is intended for delivery of the stent to the pancreatic duct (PD): Used to drain pancreatic ducts	urine from the kidney to the bladder.
Classification/ Regulation	Class II 21 CFR 876.5010	Class II 21 CFR 876.5010	Class II 21 CFR 876.4620
Product Code	FGE	FGE	FAD
Device Description Summary	The "ARCHIMEDES Fast Biodegradable Pancreatic Stent" device is a single use, synthetic, biodegradable, polymeric implant, composed of polymers used extensively in implantable and absorbable medical devices.	The Advanix™ Pancreatic Stents are provided in straight or single pigtail shape. The straight shape stents have trailing barbs and/or leading barbs depending on application, a rounded or tapered leading end tip to facilitate access through the papilla, and a rounded trailing end to abut the push catheter portion of the delivery system or stent pusher. The single pigtail stent may or may not have leading end barbs depending on	The Microvasive Temporary Ureteral Drainage Stent is 6 Fr x 26.5 cm, with an open-ended coil at each end. The stent is an extruded polymeric tube made of a reversible cross-linked alginate polymer with an incorporated radiopacifier. The device is placed, using standard ureteral stent placement techniques that can be placed transurethrally, percutaneously or via open surgery using

Device Properties	ARCHIMEDES Biodegradable Pancreatic Stent (Subject Device)	AdvaniX™ Pancreatic Stent and NaviFlexQm Rapid Exchange (RX) Pancreatic Delivery System and Pushers (Primary Predicate) K133700	Microvasive Temporary Ureteral Drainage Stent (Reference Device) K013784
		application. Some stents have lateral drainage holes in the pigtails. a tapered or rounded leading end tip. and a rounded trailing end. All stents have either an endoscopic marker, fluoroscopic marker, or both on the trailing or leading end of the stent to assist with depth of placement in the pancreatic duct. The location and presence of an endoscopic or fluoroscopic marker is dependent on the length and diameter size of the stent. Some codes have side port holes in the body of the stent.	endoscopic and/or radiographic techniques.
Accessories	The following accessories are required for use of the ARCHIMEDES stent. Of the accessories listed below, only the introducer sleeve is supplied with the ARCHIMEDES stent. • Introducer sleeve (supplied with ARCHIMEDES) • Therapeutic duodenoscope with a 4.2mm working channel	Stent is used with appropriate delivery system or stent pushers.	

Device Properties	ARCHIMEDES Biodegradable Pancreatic Stent (Subject Device)	AdvaniX™ Pancreatic Stent and NaviFlexQm Rapid Exchange (RX) Pancreatic Delivery System and Pushers (Primary Predicate) K133700	Microvasive Temporary Ureteral Drainage Stent (Reference Device) K013784
	• Guidewire: up to 0.035” • Pushing catheter: size dependent on physician’s preference		
Dimensions	The stent is ofered in outer diameters of 2.0mm, 2.6mm, or 3.4 mm, and in various lengths to accommodate variations in pancreatic anatomy across individuals (40, 60, 80, 100, 125, 150, 175, 200, and 225 mm).	3F, 4F, 5F, 7F, 10F	6 Fr x 26.5 cm
Biocompatibility	Stent is contact with tissue/bone for a permanent duration (>30 days). Accordingly, the device has been tested per GLP for biocompatibility endpoints in accordance with ISO 10993-1: 2009.	The proposed Boston Scientific Advanix Pancreatic Stent and NaviFlex Rapid Exchange (RX) Pancreatic Delivery System and Pushers were evaluated in accordance with EN ISO 10993-1:2009- Evaluation and Testing within a risk management system. The following tests were performed on the stent: Cytotoxicity, Irritation, Sensitization, Acute Systemic Toxicity, Subchronic Toxicity, Genotoxicity, Implant, USP Physicochemnical, and Latex.	The device meets the biocompatibility requirements of IS0 10993 for its intended use.
Sterilization	Sterile, EtOH	Not Specified	Not Specified

Device Properties	ARCHIMEDES Biodegradable Pancreatic Stent (Subject Device)	AdvaniX™ Pancreatic Stent and NaviFlexQm Rapid Exchange (RX) Pancreatic Delivery System and Pushers (Primary Predicate) K133700	Microvasive Temporary Ureteral Drainage Stent (Reference Device) K013784
Singe Use/Reuse	Single use only	Single use only	Single use only

8. Performance Data

Non-clinical performance

The proposed device meets the requirements of ISO 10993 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a risk management process", ISO 11135-1 "Sterilization of Health Care products - Ethylene Oxide - Part 1: Requirements for Development, Validation, and Routine Control of Sterilization processes for Medical Devices", and ISO 10993-7 "Biological evaluation of medical devices - Part 7: ethylene oxide sterilization residuals".

The following Biocompatibility tests were performed on the ARCHIMEDES™ Biodegradable Pancreatic Stent: MEM Elution Cytotoxicity; Implantation; Guinea Pig Maximization Sensitization; 28 Day Dual Route IV/IP Systemic Toxicity; Acute Systemic Injection; Intracutaneous Reactivity; and Material Mediated Pyrogen. In addition, the results of chemical extractable studies and Toxicological Risk Assessment are provided which meet FDA's Guidance document, entitled, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."

The proposed device bench testing is in alignment with FDA guidance document, "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions". The following bench tests were performed on the ARCHIMEDES™ Biodegradable Pancreatic Stent: Visual Inspection; Outer diameter, Length; Stent Swelling Characterization; Flow Rate; Inherent Viscosity; Guidewire Compatibility; Endoscope Compatibility; Introducer Sleeve Compatibility; Simulated Use; Trackability; Pushability; Flexibility/Kink Resistance; Retraction Force; Tensile Strength; Fluoroscopic Visibility; and Degradation.
All tests met required acceptance criteria, therefore supporting the finding of substantial equivalence.

Clinical studies

The safety and efficacy of ARCHIMEDES™ Biodegradable Pancreatic Stent is also supported by eight clinical studies. The studies were conducted in various settings, including single-center and multicenter, prospective and retrospective, randomized and non-randomized designs. They included a diverse range of patients with different indications for stent placement and a variety of pancreatic conditions. The studies collectively evaluated various aspects of the ARCHIMEDES Fast stent, including its safety, efficacy, clinical performance, degradation profile, and technical success.

9. Conclusion

Q3 Medical LLC has demonstrated through its bench and clinical studies that the proposed ARCHIMEDES™ Biodegradable Pancreatic Stent is substantially equivalent to the legally marketed predicate device Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX) Pancreatic Delivery System and Pushers (K133700).