July 27, 2026

Q3 Medical USA, LLC (C/O Q3 Medical Devices Ltd.)
% John J. Smith
Partner
Hogan Lovells US LLP
Columbia Sq.
555 Thirteenth St., NW
Washington, D.C., D.C. 20004

Re: K260835
Trade/Device Name: ARCHIMEDES Biodegradable Stent (Medium)
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter And Accessories
Regulatory Class: Class II
Product Code: FGE
Dated: June 18, 2026
Received: June 22, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

ANTHONY LEE -S

Anthony Lee, Ph.D., MBA
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K260835

Device Name
ARCHIMEDES Biodegradable Stent (Medium)

Indications for Use *(Describe)*
The ARCHIMEDES Biodegradable Stent (Medium) is intended to drain biliary ducts in patients indicated for biliary duct stenting.

The ARCHIMEDES Biodegradable Stent (Medium) is intended to drain pancreatic ducts in patients indicated for pancreatic duct stenting.

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.

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510(k) Summary

ARCHIMEDES™ Biodegradable Stent (Medium)

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:	March 13, 2026

2. Device

Trade Name:	ARCHIMEDES™ Biodegradable Stent (Medium)
Common Name:	Biliary Stent, 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 (Pancreatic indication)

Trade Name:	ARCHIMEDES™ Biodegradable Pancreatic Stent (Fast)
Clearance Number:	K243412
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

4. Predicate Device (Biliary indication)

Trade Name:	Advanix™ Biliary Stent with NaviFlex™ RX Delivery System
Clearance Number:	K203162
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

5. Device Description (Pancreatic and biliary indications)

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

The ARCHIMEDES™ Medium 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 biliary and 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 biliary and 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 maintain 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 20 days. Full-degradation or no stent presence is reached within <161 days.

6. Indications for Use (Pancreatic indication)

The ARCHIMEDES™ Biodegradable Stent (Medium) is intended to drain pancreatic ducts in patients indicated for pancreatic duct stenting.

7. Indications for Use) Biliary indication)

The ARCHIMEDES™ Biodegradable Stent (Medium) is intended to drain biliary ducts in patients indicated for biliary duct stenting.

8. Comparison to the Predicate Device (Pancreatic indication)

The ARCHIMEDES™ Biodegradable Stent (Medium) is substantially equivalent to the currently marketed ARCHIMEDES™ Biodegradable Pancreatic Stent (Fast) (K243412) as follows: same intended use and principles of operations, same packaging and sterilization methods; and similar technological characteristics.

The ARCHIMEDES™ Medium stent shares key technological characteristics with the predicate device in that they are both implantable stents intended to drain pancreatic ducts.

The main technological difference between the ARCHIMEDES™ Medium and the predicate device is material composition and degradation profile. The ARCHIMEDES™ Medium stent is designed to reach minimal strength retention in about 20 days whereas the predicate device reaches minimal strength retention in about 12 days. This difference does not raise new questions of safety or effectiveness. The fundamental mechanism of action, maintenance of ductal patency and facilitation of physiological drainage, remains the same.

Device Properties	ARCHIMEDES Biodegradable Stent (MEDIUM) (Subject Device)	ARCHIMEDES Biodegradable Pancreatic Stent (FAST) (Predicate Device) K243412
Intended Use/Indications for Use	The ARCHIMEDES Biodegradable Pancreatic Stent – Medium is intended to drain pancreatic ducts in patients indicated for pancreatic duct stenting.	The ARCHIMEDES Biodegradable Pancreatic Stent – Fast is intended to drain pancreatic ducts in patients indicated for pancreatic duct stenting. The ARCHIMEDES Biodegradable Pancreatic Stent - Fast is intended to be delivered through the working channel of a therapeutic endoscope using a guidewire with

Device Properties	ARCHIMEDES Biodegradable Stent (MEDIUM) (Subject Device)	ARCHIMEDES Biodegradable Pancreatic Stent (FAST) (Predicate Device) K243412
		a maximum outer diameter of 0.035 inches and a pushing catheter of between 5 to 10 French.
Classification/ Regulation	Class II 21 CFR 876.5010	Class II 21 CFR 876.5010
Product Code	FGE	FGE
Device Description Summary	The ARCHIMEDES Biodegradable Pancreatic Stent - Medium device is a single use, synthetic, biodegradable, polymeric implant, composed of polymers used extensively in implantable and absorbable medical devices. It comprises Polydioxanone (PDO) and Barium Sulphate ($BaSO_4$).	The ARCHIMEDES Biodegradable Pancreatic Stent - Fast device is a single use, synthetic, biodegradable, polymeric implant, composed of polymers used extensively in implantable and absorbable medical devices. It comprises Polydioxanone (PDO), Polyethylene Glycol (PEG) and Barium Sulphate ($BaSO_4$).
Technological Characteristics	Material: 85% wt Polydioxanone 15% wt Barium Sulfate Degradation: Minimum strength retention of 10% is reached in 20 days Design: Dual drainage – 1. Two external spiral channels that form a double helical twist. 2. Central internal guidewire lumen. Both allow for ductal flow on both the external surfaces and through the internal lumen of the stent. The stent has a form designed to fit the natural curvature of the anatomy. The	Material: 68% wt Polydioxanone 17% wt Polyethylene Glycol 15% wt Barium Sulfate Degradation: Minimum strength retention of 10% is reached in 12 days Design: Dual drainage – 1. Two external spiral channels that form a double helical twist. 2. Central internal guidewire lumen. Both allow for ductal flow on both the external surfaces and through the internal lumen of the stent. The stent has a form designed to fit the natural curvature of the anatomy. The

Device Properties	ARCHIMEDES Biodegradable Stent (MEDIUM) (Subject Device)	ARCHIMEDES Biodegradable Pancreatic Stent (FAST) (Predicate Device) K243412
	stents contain tapered tips to allow for atraumatic insertion into the papilla. The stent contains flap and split end features to minimize migration: the 6 Fr (2.0 mm diameter) model contains a flap and split end feature and the 8 Fr (2.6 mm) and 10 Fr (3.4 mm) models contain a flap on each end. Diameters: 2.0 mm (6Fr), 2.6 mm (8Fr), 3.4 mm (10Fr) Lengths: 2.0 mm Ø – 40, 60, 80, 100, 125, 150, 175 mm 2.6 and 3.4 mm Ø – 40, 60, 80, 100, 125, 150, 175, 200, 225 mm	stents contain tapered tips to allow for atraumatic insertion into the papilla. The stent contains flap and split end features to minimize migration: the 6 Fr (2.0 mm diameter) model contains a flap and split end feature and the 8 Fr (2.6 mm) and 10 Fr (3.4 mm) models contain a flap on each end. Diameters: 2.0 mm (6Fr), 2.6 mm (8Fr), 3.4 mm (10Fr) Lengths: 2.0 mm Ø – 40, 60, 80, 100, 125, 150, 175 mm 2.6 and 3.4 mm Ø – 40, 60, 80, 100, 125, 150, 175, 200, 225 mm
Accessories	The following accessories are required for use of the ARCHIMEDES MEDIUM 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 • Guidewire: up to 0.035” • Pushing catheter: size dependent on physician’s preference • Fluoroscopy	The following accessories are required for use of the ARCHIMEDES FAST 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 • Guidewire: up to 0.035” • Pushing catheter: size dependent on physician’s preference • Fluoroscopy
Dimensions	The stent is offered in outer diameters of 2.0mm, 2.6mm, or 3.4	The stent is offered in outer diameters of 2.0mm, 2.6mm, or 3.4

Device Properties	ARCHIMEDES Biodegradable Stent (MEDIUM) (Subject Device)	ARCHIMEDES Biodegradable Pancreatic Stent (FAST) (Predicate Device) K243412
	mm, and in various lengths to accommodate variations in pancreatic anatomy across individuals (40, 60, 80, 100, 125, 150, 175, 200, and 225 mm).	mm, and in various lengths to accommodate variations in pancreatic anatomy across individuals (40, 60, 80, 100, 125, 150, 175, 200, and 225 mm).
Biocompatibility	Stent is contact with tissue/bone for a permanent duration (>30 days). Accordingly, the device has been tested per GLP for the following biocompatibility endpoints in accordance with ISO 10993-1: 2009: • Cytotoxicity per ISO 10993-5; • Sensitization per ISO 10993-10; • Irritation or intracutaneous reactivity per ISO 10993-10; • Acute systemic toxicity per ISO 10993-11; • Subacute/subchronic toxicity per ISO 10993-11; • Implantation per ISO 10993-6; and • Material-mediated pyrogenicity per ISO 10993-11. • 28 Day Dual Route IV/IP Systemic Toxicity per ISO 10993-11 • Chemical Extractable Studies and Toxicological Risk Assessment per FDA Guidance "Use of International Standard ISO 10993-1"	Stent is contact with tissue/bone for a permanent duration (>30 days). Accordingly, the device has been tested per GLP for the following biocompatibility endpoints in accordance with ISO 10993-1: 2009: • Cytotoxicity per ISO 10993-5; • Sensitization per ISO 10993-10; • Irritation or intracutaneous reactivity per ISO 10993-10; • Acute systemic toxicity per ISO 10993-11; • Subacute/subchronic toxicity per ISO 10993-11; • Implantation per ISO 10993-6; and • Material-mediated pyrogenicity per ISO 10993-11. • 28 Day Dual Route IV/IP Systemic Toxicity per ISO 10993-11 • Chemical Extractable Studies and Toxicological Risk Assessment per FDA Guidance "Use of International Standard ISO 10993-1"
Sterilization	The device meets the requirements of ISO 11135-1 "Sterilization of Health Care products - Ethylene Oxide - Part 1: Requirements for Development, Validation, and	The device meets the requirements of ISO 11135-1 "Sterilization of Health Care products - Ethylene Oxide - Part 1: Requirements for Development, Validation, and

Device Properties	ARCHIMEDES Biodegradable Stent (MEDIUM) (Subject Device)	ARCHIMEDES Biodegradable Pancreatic Stent (FAST) (Predicate Device) K243412
	Routine Control of Sterilization processes for Medical Devices", and ISO 10993-7 "Biological evaluation of medical devices - Part 7: ethylene oxide sterilization residuals".	Routine Control of Sterilization processes for Medical Devices", and ISO 10993-7 "Biological evaluation of medical devices - Part 7: ethylene oxide sterilization residuals".
Singe Use/Reuse	Single use only	Single use only

9. Comparison to the Predicate Device (Biliary indication)

The ARCHIMEDES™ Biodegradable Stent (Medium) is substantially equivalent to the currently marketed Advanix™ Biliary Stent with NaviFlex™ RX Delivery System (K203162) as follows: same intended use and principles of operations, same packaging and sterilization methods; and similar technological characteristics.

The ARCHIMEDES™ Medium stent shares key technological characteristics with the predicate device in that they are both implantable stents intended to drain biliary ducts.

The main technological difference between the ARCHIMEDES™ Medium and the proposed predicate device is the stent material. The ARCHIMEDES stent is made of a biodegradable 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 difference does not raise new questions of safety or effectiveness. The ARCHIMEDES™ Medium stent operates in the same manner as existing non-biodegradable biliary stents for which the risks are well understood and adequately mitigated through general and special controls.

Device Properties	ARCHIMEDES Biodegradable Biliary Stent – MEDIUM degrading (Subject Device)	Advanix Biliary Stent with NaviFlex RX Delivery System (Primary Predicate) K203162
Intended Use/Indications for Use	The ARCHIMEDES Biodegradable Biliary Stent – Medium is intended to drain biliary ducts in patients indicated for biliary duct stenting.	Advanix™ Biliary Stent with NaviFlex™ RX Delivery System is intended for delivery of the stent to the biliary tract for drainage of the bile ducts, for splinting of a bile duct

Device Properties	ARCHIMEDES Biodegradable Biliary Stent – MEDIUM degrading (Subject Device)	Advanix Biliary Stent with NaviFlex RX Delivery System (Primary Predicate) K203162
		during healing, or for providing bile duct patency in a stricture or past a stone.
Classification/ Regulation	Class II 21 CFR 876.5010	Class II 21 CFR 876.5010
Product Code	FGE	FGE
Device Description Summary	The ARCHIMEDES Biodegradable Biliary Stent – Medium device is a single use, synthetic, biodegradable, polymeric implant, composed of polymers used extensively in implantable and absorbable medical devices. It comprises of Polydioxanone (PDO) and Barium Sulphate ($BaSO_4$).	The Advanix™ Biliary Stent with NaviFlex™ RX Delivery System consists of biliary plastic stents and delivery system catheters. They are sold separately or in a pre-loaded configuration, in which a stent comes attached to the catheter via a suture. The system is comprised of two (2) primary components: stent and delivery catheter with a locking mechanism. The Advanix Biliary Stent allows for drainage of the biliary duct by preventing closure and maintaining the patency of the biliary duct. These biliary stents are provided in center bend and duodenal bend shapes and have leading and trailing barbs, a tapered leading end tip to facilitate access through the papilla, and a rounded tailing end to match the profile of the push catheter portion of the delivery system.
Technological Characteristics	Material: 85% wt Polydioxanone 15% wt Barium Sulfate Degradation:	Material: Stent is constructed of a radiopaque (RO) polymer. Tips:

Device Properties	ARCHIMEDES Biodegradable Biliary Stent – MEDIUM degrading (Subject Device)	Advanix Biliary Stent with NaviFlex RX Delivery System (Primary Predicate) K203162
	Minimum strength retention of 10% is reached in 20 days Design: Dual drainage – 1. Two external spiral channels that form a double helical twist. 2. Central internal guidewire lumen. Both allow for ductal flow on both the external surfaces and through the internal lumen of the stent. The stent has a form designed to fit the natural curvature of the anatomy. The stents contain tapered tips to allow for atraumatic insertion into the papilla. The stent contains flap and split end features to minimize migration: the 6 Fr (2.0 mm diameter) model contains a flap and split end feature and the 8 Fr (2.6 mm) and 10 Fr (3.4 mm) models contain a flap on each end. Diameters: 2.0 mm (6Fr), 2.6 mm (8Fr), 3.4 mm (10Fr) Lengths: 2.0 mm Ø – 40, 60, 80, 100, 125, 150, 175 mm 2.6 and 3.4 mm Ø – 40, 60, 80, 100, 125, 150, 175, 200, 225 mm	The leading end has a tapered tip and the trailing end of the stent has rounded tip. Markers: Trailing end of stent has RO markers for placement guidance. Shapes: Center bend, duodenal bend, and double pigtail Barbs: Stents have leading and trailing barbs except for pigtail shape. Diameters: 7 F, 8.5 F, and 10F Lengths: 5 cm up to 18 cm Delivery system: NaviFlex™ RX delivery catheter has an ergonomic handle and locking mechanism for controlled deployment and repositionability. Compatibility with standard guidewires and endoscope working channels. Fluoroscopic and endoscopic markers on the delivery system to assist accurate placement.
Accessories	The following accessories are required for use of the ARCHIMEDES Medium stent. Of the accessories listed below, only the	The following accessories are required for use of the Advanix Biliary Stent with NaviFlex RX Delivery System.

Device Properties	ARCHIMEDES Biodegradable Biliary Stent – MEDIUM degrading (Subject Device)	Advanix Biliary Stent with NaviFlex RX Delivery System (Primary Predicate) K203162
	introducer sleeve is supplied with the ARCHIMEDES Medium stent. • Introducer sleeve (supplied with ARCHIMEDES) • Therapeutic duodenoscope with a 4.2mm working channel • Guidewire: up to 0.035” • Pushing catheter: size dependent on physician’s preference • Fluoroscopy	• Therapeutic duodenoscope with a 4.2mm working channel • Guidewire: up to 0.035” • RX Locking device • Fluoroscopy
Dimensions	The stent is offered in outer diameters of 2.0 mm (6 F), 2.6 mm (8 F), or 3.4 mm (10 F), and in various lengths to accommodate variations in pancreatic anatomy across individuals (40, 60, 80, 100, 125, 150, 175, 200, and 225 mm).	The stent is offered in outer diameters of 7 F, 8.5 F, and 10F, and in various lengths to accommodate variations in biliary anatomy across individuals (5 cm up to 18 cm).
Biocompatibility	Stent is contact with tissue/bone for a permanent duration (>30 days). Accordingly, the device has been tested per GLP for the following biocompatibility endpoints in accordance with ISO 10993-1: 2009: • Cytotoxicity per ISO 10993-5; • Sensitization per ISO 10993-10; • Irritation or intracutaneous reactivity per ISO 10993-10; • Acute systemic toxicity per ISO 10993-11; • Subacute/subchronic toxicity per ISO 10993-11; • Implantation per ISO 10993-6; and • Material-mediated pyrogenicity per ISO 10993-11.	The device meets the requirements of ISO 10993 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a risk management process”. The following Biocompatibility tests were performed on the Advanix™ Biliary Stent with NaviFlex™ RX Delivery System: MEM Elution Cytotoxicity; Guinea Pig Maximization Sensitization; Intracutaneous Reactivity; Acute Systemic Injection; and Implantation. In addition, the results of chemical extractable studies are provided which meet FDA’s Guidance document, entitled, “Use of International

Device Properties	ARCHIMEDES Biodegradable Biliary Stent – MEDIUM degrading (Subject Device)	Advanix Biliary Stent with NaviFlex RX Delivery System (Primary Predicate) K203162
	• 28 Day Dual Route IV/IP Systemic Toxicity per ISO 10993-11 • Chemical Extractable Studies and Toxicological Risk Assessment per FDA Guidance "Use of International Standard ISO 10993-1"	Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."
Sterilization	The device meets the requirements of 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 device meets the requirements of 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".
Singe Use/Reuse	Single use only	Single use only

10. 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: 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 Stent (Medium): Visual Inspection; Outer diameter, Length; 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 Stent (Medium) is also supported by five 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 and biliary conditions. The studies collectively evaluated various aspects of the ARCHIMEDES™ Biodegradable Stent (Medium), including its safety, efficacy, clinical performance, surgical and endoscopic placement, degradation profile, and technical success.

11. Conclusion

Q3 Medical LLC has demonstrated through its bench and clinical studies that the proposed ARCHIMEDES™ Biodegradable Stent (Medium) is substantially equivalent to the legally marketed predicate devices ARCHIMEDES™ Biodegradable Pancreatic Stent (Fast) (K243412) and Advanix™ Biliary Stent with NaviFlex™ RX Delivery System (K203162).