

K243412 ARCHIMEDES Biodegradable Pancreatic StentJul 16, 2025
257 days to decisionK243412 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k243412/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Stents, Drains And Dilators For The Biliary Ducts (FGE) |
| Date received | Nov 1, 2024 |
| Decision date | Jul 16, 2025 |
| Days to decision | 257 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Q3 Medical USA, LLC (C/O Q3 Medical Devices Ltd.) |
| Location | Charlotte, NC, US |
| Contact | Eric Mangiardi |
| 510(k) history | 1 submissions · 1 cleared · 2025-2025 |

REGULATORY CONSULTANT

| | |
|-----------------|-----------------------------|
| Consulting firm | Hogan Lovells US LLP |
| Contact | John J. Smith |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**CLINICAL EVIDENCE - NCT03767166****The Archimedes Biodegradable Biliary and Pancreatic Stents**

| | |
|-------------------|---|
| Status | Completed - <i>No results published to ClinicalTrials.gov</i> |
| Enrollment | 30 patients (actual) |
| Study sites | 1 site |
| Condition studied | Pancreatic Diseases |
| Study type | Observational |
| Completion date | Dec 31, 2020 |
| Sponsor | Istituto Clinico Humanitas (Other) |

Primary outcome**Biodegradation time**Source: [ClinicalTrials.gov](https://clinicaltrials.gov) / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03767166