FDA 510(k) Premarket Notification

K260835 ARCHIMEDES Biodegradable Stent (Medium)

CLEARED

Jul 27, 2026
136 days to decision

K260835 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k260835/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Mar 13, 2026
Decision date	Jul 27, 2026
Days to decision	136 days
Third-party review	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	2 submissions · 2 cleared · 2025-2026