

K082093 BULLSEYE BILIARY STENT SYSTEMJul 29, 2009
370 days to decisionK082093 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k082093/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jul 24, 2008
Decision date	Jul 29, 2009
Days to decision	370 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Squareone
Location	Mountain View, CA, US
Contact	Eric Ankerud
510(k) history	1 submissions · 0 cleared · 2009-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k082093/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 23, 2026