

K082995 SMART DILATORFeb 6, 2009
121 days to decisionK082995 · Product code: **KNQ** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k082995/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Esophageal (KNQ)
Date received	Oct 8, 2008
Decision date	Feb 6, 2009
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Safestitch Medical
Location	Miami, FL, US
Contact	MARIO ARBESU
510(k) history	1 submissions · 1 cleared · 2009-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k082995/> 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