FDA 510(k) Premarket Notification

K990808 PBN DILATORS

CLEARED

Nov 26, 1999
260 days to decision

K990808 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k990808/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Mar 11, 1999
Decision date	Nov 26, 1999
Days to decision	260 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medical Device Technologies, Inc.**
Location	Gainsville, FL, US
Contact	KARL SWARTZ
510(k) history	46 submissions · 46 cleared · 1992-2010