FDA 510(k) Premarket Notification

K052267 SUPERCATH V

CLEARED

Oct 27, 2006
434 days to decision

K052267 · Product code: **FIE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k052267/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Fistula (FIE)
Date received	Aug 19, 2005
Decision date	Oct 27, 2006
Days to decision	434 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Togo Medikit Co., Ltd.**
Location	Chiyoda-Ku Tokyo101 Japan, JP
Contact	FUMIAKI KANAI
510(k) history	17 submissions · 17 cleared · 1986-2024