FDA 510(k) Premarket Notification

K012556 REPROCESSED GUIDEWIRES

CLEARED

Apr 29, 2002
264 days to decision

K012556 · Product code: **NML** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k012556/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Biliary, Reprocessed (NML)
Date received	Aug 8, 2001
Decision date	Apr 29, 2002
Days to decision	264 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sterilmed, Inc.**
Location	Plymouth, MN, US
Contact	PATRICK FLEISCHHACKER
510(k) history	64 submissions · 64 cleared · 2001-2024