FDA 510(k) Premarket Notification

K000845 MODIFICATION TO JMS A.V. FISTULA NEEDLE SET

CLEARED

Apr 10, 2000
26 days to decision

K000845 · Product code: **FIE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k000845/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Needle, Fistula (FIE)
Date received	Mar 15, 2000
Decision date	Apr 10, 2000
Days to decision	26 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Jms Co., Ltd.**
Location	Hiroshima, JP
Contact	KEISUKE URATOMI
510(k) history	24 submissions · 24 cleared · 1985-2001