FDA 510(k) Premarket Notification

K001496 A.V. FISTULA NEEDLE

CLEARED

Aug 1, 2000
78 days to decision

K001496 · Product code: **FIE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k001496/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Fistula (FIE)
Date received	May 15, 2000
Decision date	Aug 1, 2000
Days to decision	78 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Exelint International, Co.**
Location	Los Angeles, CA, US
Contact	ARMAND HAMID
510(k) history	7 submissions · 7 cleared · 2000-2025