FDA 510(k) Premarket Notification

K992653 SHELLY PROTECTED AV FISTULA NEEDLE

CLEARED

Oct 27, 1999
82 days to decision

K992653 · Product code: **FIE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k992653/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Fistula (FIE)
Date received	Aug 6, 1999
Decision date	Oct 27, 1999
Days to decision	82 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Diasol, Inc.**
Location	North Hollywood, CA, US
Contact	MONICA ABELES
510(k) history	10 submissions · 10 cleared · 1999-2014