FDA 510(k) Premarket Notification

K003123 RENAX A.V. FISTULA NEEDLE SETS

CLEARED

May 4, 2001
211 days to decision

K003123 · Product code: **FIE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k003123/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Fistula (FIE)
Date received	Oct 5, 2000
Decision date	May 4, 2001
Days to decision	211 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sunder Biomedical Tech. Co., Ltd.**
Location	Taichung City, TW
Contact	TONY HUNG
510(k) history	3 submissions · 3 cleared · 2001-2003