

K003123 RENAX A.V. FISTULA NEEDLE SETSMay 4, 2001
211 days to decisionK003123 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k003123/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026