FDA 510(k) Premarket Notification

K012598 REPROCESSED LAPAROSCOPIC ELECTRIC INSTUMENTS

CLEARED

Nov 7, 2001
89 days to decision

K012598 · Product code: **NUJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k012598/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation Accessories, Laparoscopic & Endoscopic, Reprocessed (NUJ)
Date received	Aug 10, 2001
Decision date	Nov 7, 2001
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sterilmed, Inc.**
Location	Plymouth, MN, US
Contact	PATRICK F FLEISCHHACKER
510(k) history	64 submissions · 64 cleared · 2001-2024