FDA 510(k) Premarket Notification

K012579 REPROCESSED PHACO TIPS

CLEARED

Nov 8, 2001
91 days to decision

K012579 · Product code: **NKX** · Ophthalmic
Source: https://www.510kdatabase.net/k012579/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Phacoemulsification, Reprocessed (NKX)
Date received	Aug 9, 2001
Decision date	Nov 8, 2001
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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