FDA 510(k) Premarket Notification

K083060 REPROCESSED HARMONIC SCALPEL

CLEARED

Jan 9, 2009
87 days to decision

K083060 · Product code: **NLQ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k083060/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single-use Reprocessed Ultrasonic Surgical Instruments (NLQ)
Date received	Oct 14, 2008
Decision date	Jan 9, 2009
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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