FDA 510(k) Premarket Notification

K003965 MRI SAFE INSTRUMENTS

CLEARED

Mar 16, 2001
84 days to decision

K003965 · Product code: **GEA** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k003965/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cannula, Surgical, General & Plastic Surgery (GEA)
Date received	Dec 22, 2000
Decision date	Mar 16, 2001
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Aesculap, Inc.**
Location	Burlingame, CA, US
Contact	LISA M MILLINGTON
510(k) history	207 submissions · 201 cleared · 1991-2025