FDA 510(k) Premarket Notification

K171869 Sutter CURIS RF Generator

CLEARED

Feb 23, 2018
246 days to decision

K171869 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k171869/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jun 22, 2017
Decision date	Feb 23, 2018
Days to decision	246 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sutter Medizintechnik GmbH**
Location	Emmendingen, DE
Contact	Ulrike Zeissler
510(k) history	9 submissions · 9 cleared · 2008-2026