FDA 510(k) Premarket Notification

K211173 maxmorespine Bipolar Electrodes

CLEARED

Jun 23, 2022
429 days to decision

K211173 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k211173/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 20, 2021
Decision date	Jun 23, 2022
Days to decision	429 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hoogland Spine Products, GmbH**
Location	Muenchen, DE
Contact	Jaap Hoogland
510(k) history	3 submissions · 3 cleared · 2009-2022