FDA 510(k) Premarket Notification

CLEARED

K232072 AMICA-GEN AGN-H-1.3, AMICA-GEN AGN 3.3, AMICA-PROBE 17G & 18G

Feb 9, 2024
212 days to decision

K232072 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k232072/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jul 12, 2023
Decision date	Feb 9, 2024
Days to decision	212 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**H.S Hospital Service S.P.A**
Location	Boca Raton, FL, US
Contact	Nevio Tosoratti
510(k) history	6 submissions · 6 cleared · 2004-2024

REGULATORY CONSULTANT

Consulting firm	**Isemed S.R.L.**
Contact	Guido Bonapace

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov