

K223856 NuEra Tight RF FamilyAug 11, 2023
231 days to decisionK223856 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k223856/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Dec 23, 2022
Decision date	Aug 11, 2023
Days to decision	231 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bios S.R.L.
Location	Silver Spring, MD, US
Contact	Manuela Brambilla
510(k) history	14 submissions · 14 cleared · 2005-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223856/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026