

K200359 NuEra Tight, NuEra Tight EMSAug 11, 2020
180 days to decisionK200359 · Product code: **PBX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k200359/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Vacuum, Radio Frequency Induced Heat (PBX)
Date received	Feb 13, 2020
Decision date	Aug 11, 2020
Days to decision	180 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200359/> 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 26, 2026