FDA 510(k) Premarket Notification

CLEARED

K260255 AVENTIX PFX System (PFX01)

Mar 27, 2026
58 days to decision

K260255 · Product code: **GEI** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k260255/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jan 28, 2026
Decision date	Mar 27, 2026
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	NOVOCLEAR Device (CLR001)

APPLICANT

Company	**Aventix Medical, Inc.**
Location	Laguna Hills, CA, US
Contact	Jetmir Palushi
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**Albatross Regulatory Consulting**
Contact	David Locke

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