

K240919 Silk Voice (SMI-04)May 3, 2024
30 days to decisionK240919 · Product code: **MIX** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k240919/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Vocal Cord Medialization (MIX)
Date received	Apr 3, 2024
Decision date	May 3, 2024
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sofregen Medical
Location	Framingham, MA, US
Contact	Vivian Ruan
510(k) history	1 submissions · 1 cleared · 2024-2024

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