

K180631 Silk VoiceNov 8, 2018
244 days to decisionK180631 · Product code: **MIX** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k180631/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Vocal Cord Medialization (MIX)
Date received	Mar 9, 2018
Decision date	Nov 8, 2018
Days to decision	244 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sofregen Medical, Inc.
Location	Medford, MA, US
Contact	Anh Hoang
510(k) history	2 submissions · 2 cleared · 2017-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180631/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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