

K183015 PuraSinusApr 12, 2019
163 days to decisionK183015 · Product code: **NHB** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k183015/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer, Ear, Nose And Throat, Synthetic, Absorbable (NHB)
Date received	Oct 31, 2018
Decision date	Apr 12, 2019
Days to decision	163 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	3-D Matrix, Inc.
Location	Waltham, MA, US
Contact	Lisa Spirio
510(k) history	7 submissions · 7 cleared · 2015-2023

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