FDA 510(k) Premarket Notification

K203754 Eustachi Ear Pressure Relief Device

CLEARED

Feb 19, 2021
58 days to decision

K203754 · Product code: **MJV** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k203754/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Inflation, Middle Ear (MJV)
Date received	Dec 23, 2020
Decision date	Feb 19, 2021
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Exercore, LLC**
Location	Shakopee, MN, US
Contact	Kevin Connelly
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**DuVal & Associates, P.A.**
Contact	Lisa Pritchard

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