FDA 510(k) Premarket Notification

K220139 QScreen

CLEARED

Aug 3, 2022
197 days to decision

K220139 · Product code: **GWJ** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k220139/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Auditory, Evoked Response (GWJ)
Date received	Jan 18, 2022
Decision date	Aug 3, 2022
Days to decision	197 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Path Medical GmbH**
Location	Fort Collins, CO, US
Contact	Johann Oswald
510(k) history	6 submissions · 6 cleared · 2010-2022