FDA 510(k) Premarket Notification

K223445 ArtiFascia

CLEARED

Aug 10, 2023
269 days to decision

K223445 · Product code: **GXQ** · Neurology
Source: https://www.510kdatabase.net/k223445/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dura Substitute (GXQ)
Date received	Nov 14, 2022
Decision date	Aug 10, 2023
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Nurami Medical , Ltd.**
Location	Haifa, IL
Contact	Hannoch Marksheid
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Janice Hogan

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