FDA 510(k) Premarket Notification

K213078 Myolift QT

CLEARED

Apr 27, 2023
581 days to decision

K213078 · Product code: **NFO** · Physical Medicine
Source: https://www.510kdatabase.net/k213078/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Transcutaneous Electrical, Aesthetic Purposes (NFO)
Date received	Sep 23, 2021
Decision date	Apr 27, 2023
Days to decision	581 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Johari Digital Healthcare Limited**
Location	Jodhpur, IN
Contact	Pooja Johari
510(k) history	3 submissions · 3 cleared · 2020-2023

REGULATORY CONSULTANT

Consulting firm	**7D Wellness**
Contact	Pooja Johari

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