FDA 510(k) Premarket Notification

K221077 Auryon Atherectomy System

CLEARED

Jun 9, 2022
58 days to decision

K221077 · Product code: **MCW** · Cardiovascular
Source: https://www.510kdatabase.net/k221077/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Apr 12, 2022
Decision date	Jun 9, 2022
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Eximo Medical, Ltd.**
Location	Rehovot, IL
Contact	Yoel Zabar
510(k) history	7 submissions · 7 cleared · 2018-2024

REGULATORY CONSULTANT

Consulting firm	**Angiodynamics**
Contact	James Welsh

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

CLINICAL EVIDENCE - NCT02556255

Safety and Effectiveness Study of Eximo's B-Laser™ Atherectomy Device for PAD Treatment

Status	Completed
Enrollment	57 patients (actual)
Study sites	2 sites
Condition studied	Peripheral Arterial Disease
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Nov 20, 2020
Sponsor	Eximo Medical Ltd. (Industry)

Primary outcome

Number of Participants With 30 Day Freedom From Major Adverse Events

Secondary outcome

Number of Participants With Perioperative (Until Discharge) Freedom From Device/Procedure* Related Adverse Events (2)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02556255