FDA 510(k) Premarket Notification

K213840 MolecuLight I:X

CLEARED

May 18, 2022
160 days to decision

K213840 · Product code: **QJF** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k213840/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Autofluorescence Imaging Adjunct Tool For Wounds (QJF)
Date received	Dec 9, 2021
Decision date	May 18, 2022
Days to decision	160 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Moleculight, Inc.**
Location	Toronto, CA
Contact	Jordan John
510(k) history	5 submissions · 4 cleared · 2018-2022

CLINICAL EVIDENCE - NCT03540004

Evaluation of MolecuLight i:X as an Adjunctive Fluorescence Imaging Tool to Clinical Signs and Symptoms for the Identification of Bacteria-containing Wounds

Status	Unknown - *No results published to ClinicalTrials.gov*
Enrollment	367 patients (actual)
Study sites	14 sites
Condition studied	Wound
Study type	Observational
Completion date	Dec 30, 2020
Sponsor	MolecuLight Inc. (Industry)

Primary outcome

Diagnostic accuracy of identifying wounds with moderate/heavy bacterial load as measured by sensitivity and specificity.

Secondary outcome

Estimation of sensitivity and specificity of MolecuLight i:X alone

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03540004