

**K210882 MolecuLight I:X**Jun 22, 2021  
89 days to decisionK210882 · Product code: **QJF** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k210882/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Autofluorescence Imaging Adjunct Tool For Wounds (QJF)
Date received	Mar 25, 2021
Decision date	Jun 22, 2021
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**CLINICAL EVIDENCE - NCT03540004**

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**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 - <i>No results published to ClinicalTrials.gov</i>
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](https://clinicaltrials.gov/study/NCT03540004)