

K233077 FlashHeal 2 (FlashHeal 2.0)Jan 18, 2024
114 days to decisionK233077 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k233077/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 26, 2023
Decision date	Jan 18, 2024
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Inwound Aps
Location	Copenhagen, DK
Contact	Otto Ømann
510(k) history	1 submissions · 1 cleared · 2024-2024

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