FDA 510(k) Premarket Notification

CLEARED

K240297 Canady Helios Cold Plasma™ XL-1000CP™ Ablation System (XL-1000CPSYS)

May 3, 2024
92 days to decision

K240297 · Product code: **OAB** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k240297/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Low Energy Direct Current Thermal Ablation System (OAB)
Date received	Feb 1, 2024
Decision date	May 3, 2024
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Us Medical Innovations, LLC**
Location	Austin, TX, US
Contact	Jerome Canady
510(k) history	5 submissions · 5 cleared · 2011-2024

REGULATORY CONSULTANT

Consulting firm	**Emergo Global Consulting, LLC**
Contact	Audrey Swearingen

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k240297/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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