

K211272 ICOONE Laser Med (also referred to as ICOONE Medical laser)Jun 22, 2021
56 days to decisionK211272 · Product code: **NUV** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k211272/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Vacuum, Light Induced Heating (NUV)
Date received	Apr 27, 2021
Decision date	Jun 22, 2021
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	I-Tech Industries Srl
Location	San Lazzaro Di Savena, IT
Contact	Gianfranco Tudico
510(k) history	2 submissions · 2 cleared · 2019-2021

REGULATORY CONSULTANT

Consulting firm	Mansour Consulting, LLC
Contact	Jay Mansour

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211272/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026