

K111831 MX-7000 MICROXELDec 19, 2011
174 days to decisionK111831 · Product code: **ONG** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k111831/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument With Microbeamfractional Output (ONG)
Date received	Jun 28, 2011
Decision date	Dec 19, 2011
Days to decision	174 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bio-Med USA, Inc.
Location	Paterson, NJ, US
Contact	YOUNG CHI
510(k) history	10 submissions · 10 cleared · 2008-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k111831/> 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