

K852121 MEDILASER MIC MODEL MEL 440-CAug 20, 1985
97 days to decisionK852121 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k852121/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 15, 1985
Decision date	Aug 20, 1985
Days to decision	97 days
Third-party review	No
Other names	30W

APPLICANT

Company	Mochida Pharmaceutical Co., Ltd.
Location	Walker, MI, US
Contact	RICHARD E FRANKO
Website	http://www.mochida.co.jp
510(k) history	4 submissions · 4 cleared · 1984-2024

Mochida Pharmaceutical Co., Ltd. is a Japanese pharmaceutical and medical device manufacturer with a manufacturing facility in Walker, US. The company develops and markets medical devices across multiple therapeutic areas, including surgical and healthcare solutions. Mochida has received FDA 510(k) clearances from total submissions, with a dominant focus on General & Plastic Surgery devices. The company's regulatory history spans from 1984 to 2024, demonstrating sustained engagement with FDA clearance pathways. Recent cleared devices include laser systems for surgical app...
