

K852122 MEDILASER MIC MODEL MEL-445C, 15WAug 20, 1985
97 days to decisionK852122 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k852122/>**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 |

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...
