

**K913191 DORNIER LASER LITHOTRIPTER IMPACT**Oct 16, 1991  
90 days to decisionK913191 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k913191/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 18, 1991
Decision date	Oct 16, 1991
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Dornier Medtech America, Inc.</b>
Location	Marietta, GA, US
Contact	CLAY DIXON
510(k) history	40 submissions · 40 cleared · 1990-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k913191/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026