

**K011322 DORNIER SAPPHIREERBIUM HANDPIECE, DORNIER  
SAPPHIRESPOT HANDPIECE**Nov 19, 2001  
202 days to decisionK011322 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k011322/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 1, 2001
Decision date	Nov 19, 2001
Days to decision	202 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011322/> 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 June 28, 2026