

K081181 SMART CO2 (SMART US 20D / ULTRASPEED, SMART CLINIC AND PERIOPULSE) SURGICAL LASERMay 5, 2008
10 days to decisionK081181 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k081181/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 25, 2008
Decision date	May 5, 2008
Days to decision	10 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cynosure, Inc.
Location	Bedford, MA, US
Contact	GEORGE CHO
510(k) history	98 submissions · 98 cleared · 1992-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081181/> 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 18, 2026