

K082423 NO!NO! SKINDec 3, 2008
103 days to decisionK082423 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k082423/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 22, 2008
Decision date	Dec 3, 2008
Days to decision	103 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Radiancy (Israel) , Ltd.
Location	Washington, DC, US
Contact	ZVI LADIN
510(k) history	11 submissions · 11 cleared · 2002-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k082423/> 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 20, 2026