

K082911 SMOOTHCOOL HR SYSTEMDec 19, 2008
80 days to decisionK082911 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k082911/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 30, 2008
Decision date	Dec 19, 2008
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Jeisys Medical, Inc.
Location	Littleton, CO, US
Contact	Kevin Walls
510(k) history	15 submissions · 15 cleared · 2008-2024

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