

K092326 SMOOTHCOOLMar 5, 2010
213 days to decisionK092326 · Product code: **ONF** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k092326/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Light Based Non-laser Surgical Instrument With Thermal Effect (ONF)
Date received	Aug 4, 2009
Decision date	Mar 5, 2010
Days to decision	213 days
Third-party review	No
Summary / Statement	Statement

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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