

K162191 NAVILAS Laser SystemNov 22, 2016
110 days to decisionK162191 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k162191/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 4, 2016
Decision date	Nov 22, 2016
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Od-Os GmbH
Location	Laguna Beach, CA, US
Contact	WINFRIED TEIWES
510(k) history	4 submissions · 4 cleared · 2009-2025

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