

K053540 INTERMEDIC DIODE LASER FAMILY 810NM AND 980NM (AND THE DELIVERY ACCESSORIES THAT ARE USED WITH THEM TO DELIVER LASER EN

Sep 6, 2006
260 days to decision

K053540 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k053540/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 20, 2005
Decision date	Sep 6, 2006
Days to decision	260 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Intermedic Arfran, SA
Location	Meza, AZ, US
Contact	KLAUS SIVEC
510(k) history	2 submissions · 2 cleared · 2006-2009

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Device record: <https://www.510kdatabase.net/k053540/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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