FDA 510(k) Premarket Notification

K050218 WAVELIGHT SINON

CLEARED

Feb 15, 2005
15 days to decision

K050218 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k050218/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 31, 2005
Decision date	Feb 15, 2005
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Wavelight Laser Technologie AG**
Location	North Reading, MA, US
Contact	MANFRED DRAX
510(k) history	8 submissions · 8 cleared · 2004-2006