FDA 510(k) Premarket Notification

K943201 CLEAN AIR

CLEARED

Feb 28, 1995
238 days to decision

K943201 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k943201/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 5, 1994
Decision date	Feb 28, 1995
Days to decision	238 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Wallach Surgical Devices, Inc.**
Location	Walker, MI, US
Contact	RAYMOND WILEY
510(k) history	27 submissions · 27 cleared · 1981-2002

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k943201/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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