FDA 510(k) Premarket Notification

K913191 DORNIER LASER LITHOTRIPTER IMPACT

CLEARED

Oct 16, 1991
90 days to decision

K913191 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k913191/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 18, 1991
Decision date	Oct 16, 1991
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Dornier Medtech America, Inc.**
Location	Marietta, GA, US
Contact	CLAY DIXON
510(k) history	40 submissions · 40 cleared · 1990-2023