FDA 510(k) Premarket Notification

K945796 SHARPLAN USIGHT 9010 LAPAROSCOPIC ULTRASOUND SYSTEM

CLEARED

May 24, 1995
177 days to decision

K945796 · Product code: **ITX** · Radiology
Source: https://www.510kdatabase.net/k945796/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Nov 28, 1994
Decision date	May 24, 1995
Days to decision	177 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sharplan Lasers, Inc.**
Location	Allendale, NJ, US
Contact	DOUG MEAD
510(k) history	78 submissions · 78 cleared · 1986-1997

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k945796/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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