FDA 510(k) Premarket Notification

K951806 OPGAL INTRAOPERATIVE VASCULAR ANGIOGRAPHY SYSTEM (IVA-2000)

CLEARED

Jul 6, 1995
78 days to decision

K951806 · Product code: **LHQ** · Radiology
Source: https://www.510kdatabase.net/k951806/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Telethermographic (adjunctive Use) (LHQ)
Date received	Apr 19, 1995
Decision date	Jul 6, 1995
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Opgal Optronic Industries**
Location	N. Attleboro, MA, US
Contact	ROSINA ROBINSION
510(k) history	1 submissions · 1 cleared · 1995-1995

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k951806/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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