FDA 510(k) Premarket Notification

K083748 IPULSE, MODEL: I150

CLEARED

Feb 2, 2009
47 days to decision

K083748 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k083748/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 17, 2008
Decision date	Feb 2, 2009
Days to decision	47 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Cyden Limited**
Location	Swansea, Wales, GB
Contact	MICHAEL KIERNAN
510(k) history	21 submissions · 21 cleared · 2004-2024