FDA 510(k) Premarket Notification

CLEARED

K071883 IPULSE, QUADRA Q4 PLATINUM SERIES, MODEL(S) 1200+SERIES 2, 1300 SERIES 2, Q4 SERIES 2

Jan 23, 2008
198 days to decision

K071883 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k071883/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 9, 2007
Decision date	Jan 23, 2008
Days to decision	198 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