FDA 510(k) Premarket Notification

K082126 RHAPSODY MRI

CLEARED

Nov 13, 2008
107 days to decision

K082126 · Product code: **LJT** · General Hospital
Source: https://www.510kdatabase.net/k082126/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Port & Catheter, Implanted, Subcutaneous, Intravascular (LJT)
Date received	Jul 29, 2008
Decision date	Nov 13, 2008
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Grantadler Corporation**
Location	Apollo Beach, FL, US
Contact	ARTHUR WARD
510(k) history	2 submissions · 2 cleared · 2008-2008