FDA 510(k) Premarket Notification

K113552 FREEDOM INGUINAL HERNIA IMPLANT

CLEARED

Aug 23, 2012
266 days to decision

K113552 · Product code: **FTL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k113552/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Dec 1, 2011
Decision date	Aug 23, 2012
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Insightra Medical**
Location	Irvine, CA, US
Contact	Wayne Noda
510(k) history	3 submissions · 3 cleared · 2012-2015