K093162 FIDELIS PLUS III D, AT FIDELIS D, POWERLASE AT D / FIDELIS PLUS III, AT FIDELIS, POWERLASE AT / FIDELIS ER III D, HT FID

CLEARED

Jan 22, 2010
108 days to decision

K093162 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k093162/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 6, 2009
Decision date	Jan 22, 2010
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Fotona D.D.**
Location	Ljubljana, SI
Contact	STOJAN TROST
510(k) history	27 submissions · 27 cleared · 1998-2015