FDA 510(k) Premarket Notification

K090281 ACCUTECH FAMILY OF POWERFLEX LASER DELIVERY DEVICES

CLEARED

Mar 4, 2009
27 days to decision

K090281 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k090281/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 5, 2009
Decision date	Mar 4, 2009
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Accutech Medical Technologies, Inc.**
Location	Pleasanton, CA, US
Contact	ANNE WORDEN
510(k) history	2 submissions · 2 cleared · 2006-2009