FDA 510(k) Premarket Notification

K142791 Spectra Soft Tissue Biopsy Needles

CLEARED

Jan 21, 2015
117 days to decision

K142791 · Product code: **KNW** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k142791/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Sep 26, 2014
Decision date	Jan 21, 2015
Days to decision	117 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spectra Medical Devices**
Location	Wilmington, MA, US
Contact	Agustin Turriza
510(k) history	2 submissions · 2 cleared · 2015-2017

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k142791/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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