FDA 510(k) Premarket Notification

K163388 XPress BCD Breast Compression Device

CLEARED

Jul 19, 2017
229 days to decision

K163388 · Product code: **POY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k163388/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Post Breast Biopsy Hemostatic Breast Compression Device (POY)
Date received	Dec 2, 2016
Decision date	Jul 19, 2017
Days to decision	229 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Xpress Bcd, LLC**
Location	Frederick, MD, US
Contact	Peter Kremers
510(k) history	1 submissions · 1 cleared · 2017-2017