

K163388 XPress BCD Breast Compression DeviceJul 19, 2017
229 days to decisionK163388 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k163388/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 1, 2026