

Berlin Heart® EXCOR® Pediatric Ventricular Assist Device (VAD)

H100004

Pediatric Advisory Committee
Panel Meeting

2017



Berlin Heart® EXCOR® **Update**

- December 16, 2011
 - HDE Approval
 - Pediatric use and allowed to make profit
 - Mandated annual safety review at the PAC
- June 6, 2017
 - PMA Approval
- June 29, 2017
 - HDE withdrawn
 - No longer required to have annual safety review at the PAC

