

**K163437 hypodermic Pinpoint™ GT Needle**Jun 23, 2017  
198 days to decisionK163437 · Product code: **PVZ** · General Hospital  
Source: <https://www.510kdatabase.net/k163437/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Non-stainless Steel Needle (PVZ)
Date received	Dec 7, 2016
Decision date	Jun 23, 2017
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>C.R. Bard, Inc.</b>
Location	Covington, GA, US
Contact	Jamie Howell
Website	<a href="https://www.bd.com">https://www.bd.com</a>
510(k) history	644 submissions · 609 cleared · 1976-2026

C.R. Bard, Inc. is a developer, manufacturer, and marketer of medical technologies headquartered in Covington, US. The company specializes in vascular medicine, urology, oncology, and surgical specialty devices. C.R. Bard maintains a strong FDA 510(k) regulatory track record with FDA 510(k) cleared devices from total submissions spanning 1976 to 2026. The company's portfolio encompasses cardiovascular devices, gastroenterology and urology products, and general surgical technologies. Recent clearances include temporary pacing electrode catheters, thrombectomy systems, and ...

---