

**K830608 USCI GRUNTZIG DILACA BALLOON DILATION**Mar 24, 1983  
27 days to decisionK830608 · Product code: LIT · Cardiovascular  
Source: <https://www.510kdatabase.net/k830608/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Feb 25, 1983
Decision date	Mar 24, 1983
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No

**APPLICANT**

---

Company	<b>C.R. Bard, Inc.</b>
Location	Covington, GA, US
Website	<a href="https://www.bd.com">https://www.bd.com</a>
510(k) history	645 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 ...

---