

**K160941 Castor, Achilles and Hermes NC PTA Balloon  
Dilatation Catheter**Dec 13, 2016  
253 days to decisionK160941 · Product code: LIT · Cardiovascular  
Source: <https://www.510kdatabase.net/k160941/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Apr 4, 2016
Decision date	Dec 13, 2016
Days to decision	253 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Brosmed Medical Co., Ltd.</b>
Location	Dongguan, CN
Contact	Tina Yin
510(k) history	8 submissions · 8 cleared · 2016-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160941/> 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 May 24, 2026