FDA 510(k) Premarket Notification

# K160256 Polux , Minerva and Atropos PTA Balloon Dilatation Catheter

**CLEARED**

Jul 29, 2016
179 days to decision

K160256 · Product code: **LIT** · Cardiovascular
Source: https://www.510kdatabase.net/k160256/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Angioplasty, Peripheral, Transluminal (LIT) |
| Date received | Feb 1, 2016 |
| Decision date | Jul 29, 2016 |
| Days to decision | 179 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

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