

**K062108 COMCASET SAFETY IV CATHETER**Aug 8, 2006  
15 days to decisionK062108 · Product code: **FOZ** · General Hospital  
Source: <https://www.510kdatabase.net/k062108/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Jul 24, 2006
Decision date	Aug 8, 2006
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Pitango Medical, Ltd.</b>
Location	Ramat Gan, IL
Contact	BEN LEVIN
510(k) history	2 submissions · 2 cleared · 2006-2007

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k062108/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026