

**K190813 CrossBay Cervical Dilator Catheter System**Aug 23, 2019  
147 days to decisionK190813 · Product code: **PON** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k190813/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Balloon, Dilation Of Cervical Canal (PON)
Date received	Mar 29, 2019
Decision date	Aug 23, 2019
Days to decision	147 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Crossbay Medical</b>
Location	San Diego, CA, US
Contact	Piush Vidyarthi
510(k) history	3 submissions · 3 cleared · 2019-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Domecus Consulting Services, LLC</b>
Contact	Cindy Domecus

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190813/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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