

**K070705 MODIFICATION TO: LATEX-FREE BIONECTOR,  
MODEL# 896.019, 896.039**Nov 30, 2007  
261 days to decisionK070705 · Product code: FOZ · General Hospital  
Source: <https://www.510kdatabase.net/k070705/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Mar 14, 2007
Decision date	Nov 30, 2007
Days to decision	261 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vygon Corp.</b>
Location	East Rutherford, NJ, US
Contact	COURTNEY SMITH
510(k) history	48 submissions · 46 cleared · 1985-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k070705/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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