

**K963981 VYGON BIONECTOR WITH EXTENSION SET**Feb 14, 1997  
134 days to decisionK963981 · Product code: **FPA** · General Hospital  
Source: <https://www.510kdatabase.net/k963981/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Oct 3, 1996
Decision date	Feb 14, 1997
Days to decision	134 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Vygon Corp.</b>
Location	East Rutherford, NJ, US
Contact	ANNE MARIE CESARIO
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/k963981/> 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 May 26, 2026