

**K010448 HORIZONS INTERNATIONAL VARICES INJECTION  
NEEDLES**May 16, 2001  
90 days to decisionK010448 · Product code: **FBK** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k010448/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Feb 15, 2001
Decision date	May 16, 2001
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Horizons Intl. Corp.</b>
Location	Aguadilla, PR, US
Contact	RAFIC SALEH
510(k) history	10 submissions · 10 cleared · 2001-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010448/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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