

**K043383 N-DO ENDOINJECTOR NEEDLE, MODEL PH00961109
AND PH00961110**Oct 27, 2005
322 days to decisionK043383 · Product code: **FBK** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k043383/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Dec 9, 2004
Decision date	Oct 27, 2005
Days to decision	322 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Physion, Inc.
Location	Short Hills, NJ, US
Contact	ERIC J NEMETH, ESQ.
510(k) history	2 submissions · 2 cleared · 2003-2005

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