FDA 510(k) Premarket Notification

K092429 ENDOGATOR

CLEARED

Nov 19, 2009
104 days to decision

K092429 · Product code: **FEQ** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k092429/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Air, Non-manual, For Endoscope (FEQ)
Date received	Aug 7, 2009
Decision date	Nov 19, 2009
Days to decision	104 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Byrne Medical, Inc.**
Location	Houston, TX, US
Contact	DON BYRNE
510(k) history	12 submissions · 12 cleared · 2003-2012