FDA 510(k) Premarket Notification

K132065 INJECTION NEEDLE

CLEARED

Jan 17, 2014
198 days to decision

K132065 · Product code: **FBK** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k132065/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Jul 3, 2013
Decision date	Jan 17, 2014
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Endochoice, Inc.**
Location	Chalotte, NC, US
Contact	THERON GOBER
510(k) history	27 submissions · 25 cleared · 2010-2016