

K133148 BIOMARC COAXIAL NEEDLEMay 13, 2014
208 days to decisionK133148 · Product code: **FBK** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k133148/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Oct 17, 2013
Decision date	May 13, 2014
Days to decision	208 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Carbon Medical Technologies, Inc.
Location	St, Paul, MN, US
Contact	ANDREW J ADAMS
510(k) history	16 submissions · 16 cleared · 2002-2025

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