FDA 510(k) Premarket Notification

CLEARED

K090217 BONEE NEEDLE FOR BLADDER INJECTIONS, MODELSNBI035, NBI070

Apr 23, 2009
84 days to decision

K090217 · Product code: **FBK** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k090217/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Jan 29, 2009
Decision date	Apr 23, 2009
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Coloplast A/S**
Location	Mchenry, IL, US
Contact	SURESH GHAL
Website	http://www.coloplast.com/
510(k) history	71 submissions · 68 cleared · 1983-2023

Coloplast A/S is a Danish multinational medical device manufacturer based in McHenry, US. The company develops and markets devices for ostomy, urology, continence, and wound care. Coloplast has received FDA 510(k) clearances from total submissions since its first clearance in 1983. The company's regulatory portfolio is dominated by Gastroenterology & Urology devices, including catheter systems, guidewires, and access sheaths. The latest clearance on record dates to 2023, reflecting the company's historical engagement with FDA regulatory pathways. Notable cleared devices i...