FDA 510(k) Premarket Notification

K173803 Omnican fine

CLEARED

Jun 11, 2018
178 days to decision

K173803 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k173803/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Dec 15, 2017
Decision date	Jun 11, 2018
Days to decision	178 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**B.Braun Medical, Inc.**
Location	Plymouth, MN, US
Contact	Kimberly Smith
Website	http://www.bbraunusa.com/
510(k) history	148 submissions · 145 cleared · 1993-2025

B.Braun Medical, Inc. is a leading medical technology company specializing in infusion therapy, vascular access, and hospital-based medical devices. The company operates with a manufacturing facility in Plymouth, Massachusetts. B.Braun Medical has maintained a strong FDA 510(k) regulatory record since 1993. The company has received FDA 510(k) clearances from total submissions. Recent clearances in 2025 demonstrate continued innovation in infusion pumps, IV catheters, and administration sets for general hospital use. The company's cleared device portfolio focuses on smart ...