

K262571 EnCor EnCompass™ Breast Biopsy and Tissue Removal System

Aug 14, 2026
21 days to decision

K262571 · Product code: KNW · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k262571/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Instrument, Biopsy (KNW)
Date received	Jul 24, 2026
Decision date	Aug 14, 2026
Days to decision	21 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bard Peripheral Vascular, Inc.
Location	Tempe, AZ, US
Contact	Jakob Wells
Website	https://www.bd.com
510(k) history	35 submissions · 31 cleared · 2004-2026

Bard Peripheral Vascular, Inc. is a medical device manufacturer based in Tempe, Arizona. The company specializes in cardiovascular and surgical devices for minimally invasive procedures. FDA 510(k) regulatory activity spans from 2004 to 2026. The company has received FDA 510(k) clearances from total submissions. Cardiovascular devices represent a dominant category, including PTA balloons, atherectomy systems, and vascular access solutions. The company remains actively engaged in device development, with the latest clearance in 2026. Recent cleared devices reflect expertis...