

K252795 ZeniCore™ Automatic Biopsy Instrument (863212100 / ZeniCore Automatic Biopsy Device 12ga x 10cm with Coaxial Introducer Kit)Feb 23, 2026
174 days to decisionK252795 · Product code: **KNW** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k252795/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Sep 2, 2025
Decision date	Feb 23, 2026
Days to decision	174 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	ZeniCore™ Automatic Biopsy Instrument (863212130 / ZeniCore Automatic Biopsy Device 12ga x 13cm with Coaxial Introducer Kit); ZeniCore™ Automatic Biopsy Instrument (863214100 / ZeniCore Automatic Biopsy Device 14ga x 10cm with Coaxial Introducer Kit); ZeniCore™ Automatic Biopsy Instrument (863214130 / ZeniCore Automatic Biopsy Device 14ga x 13cm with Coaxial

APPLICANT

Company	Argon Medical Devices, Inc.
Location	Athens, TX, US
Contact	Jacquelyn Huyghue
Website	https://www.argonmedical.com
510(k) history	20 submissions · 20 cleared · 2007-2026

Argon Medical Devices, Inc. manufactures specialty interventional medical devices. The company is based in Athens, US. Argon has received FDA 510(k) clearances from total submissions since 2007. The company specializes in Cardiovascular devices, which represent the dominant focus of its regulatory portfolio. The latest clearance was in 2026, reflecting continued active development and market engagement. Argon's cleared device portfolio includes thrombectomy systems, vascular access devices, biopsy instruments, and retrieval kits. The company also offers custom product sol...
