

K241042 SafeSharp Transseptal Needle (CLICK071, CLICK171, CLICK098, CLICK198)

May 17, 2024
30 days to decision

K241042 · Product code: **DRC** · Cardiovascular
Source: <https://www.510kdatabase.net/k241042/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Trocar (DRC)
Date received	Apr 17, 2024
Decision date	May 17, 2024
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pressure Products Medical Device Manufacturing, LLC
Location	Morton, PA, US
Contact	Andrew Armour
510(k) history	9 submissions · 9 cleared · 2017-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k241042/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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