

K191195 PiccGuardJan 3, 2020
245 days to decisionK191195 · Product code: **PZW** · General Hospital
Source: <https://www.510kdatabase.net/k191195/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter Access Cover, Tamper-resistant (PZW)
Date received	May 3, 2019
Decision date	Jan 3, 2020
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Piccguard, LLC
Location	Beloit, WI, US
Contact	Katie Justus
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Smith Associates
Contact	E.J. Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191195/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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