

K212201 PENTAX Medical Auto Leakage Tester SHA-P6Oct 1, 2021
79 days to decisionK212201 · Product code: **PCV** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k212201/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Leak Tester (PCV)
Date received	Jul 14, 2021
Decision date	Oct 1, 2021
Days to decision	79 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pentax of America, Inc.
Location	West Cadwell, NJ, US
Contact	William Goeller
510(k) history	44 submissions · 44 cleared · 2012-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212201/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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