

K162297 Diazyme Procalcitonin (PCT) Assay, Diazyme Procalcitonin (PCT) Calibrator Set, Diazyme Procalcitonin (PCT) Control SetApr 18, 2017
245 days to decisionK162297 · Product code: **PTF** · Microbiology
Source: <https://www.510kdatabase.net/k162297/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay To Measure Pct To Aid In The Risk Assessment Of Critically Ill Patients On Their First Day Of Icu Admission (PTF)
Date received	Aug 16, 2016
Decision date	Apr 18, 2017
Days to decision	245 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Diazyme Laboratories
Location	Irvine, CA, US
Contact	Abhijit Datta
510(k) history	41 submissions · 41 cleared · 2003-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162297/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 31, 2026