

K251630 Atellica IM Total PSA II (tPSAII)Jan 5, 2026
222 days to decisionK251630 · Product code: **LTJ** · Immunology
Source: <https://www.510kdatabase.net/k251630/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prostate-specific Antigen (psa) For Management Of Prostate Cancers (LTJ)
Date received	May 28, 2025
Decision date	Jan 5, 2026
Days to decision	222 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics, Inc.
Location	New York, NY, US
Contact	Kira Gordon
Website	https://www.siemens-healthineers.com
510(k) history	152 submissions · 151 cleared · 2008-2026

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