FDA 510(k) Premarket Notification

K240041 IVD CAPSULE PSP

CLEARED

Sep 25, 2024
264 days to decision

K240041 · Product code: **SCX** · Microbiology
Source: https://www.510kdatabase.net/k240041/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay For Host Biomarkers Of Sepsis (SCX)
Date received	Jan 5, 2024
Decision date	Sep 25, 2024
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	abioSCOPE

APPLICANT

Company	**Abionic SA**
Location	Epalinges, CH
Contact	Iwan Märki
510(k) history	1 submissions · 1 cleared · 2024-2024

CLINICAL EVIDENCE - NCT04105699

Evaluation of Immunoassay Measurements of Pancreatic Stone Protein Performed on abioSCOPE® Device With the PSP Assay on ICU Patients at Risk of Sepsis as an Aid in Identifying Sepsis

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	544 patients (actual)
Study sites	5 sites
Condition studied	Sepsis
Study type	Observational
Completion date	Dec 28, 2023
Sponsor	Abionic SA (Industry)

Primary outcome

Ability of the abioSCOPE PSP assay performed on day 1 of a participant's ICU admission to correctly identify those with sepsis.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04105699