

K191364 T-TAS 01 Total Thrombus-formation Analysis System Instrument, PL Chip for T-TAS 01, PL Chip Reservoir Set for T-TAS 01, BAPA tube for T-TAS 01Feb 14, 2020
268 days to decisionK191364 · Product code: JOZ · Hematology
Source: <https://www.510kdatabase.net/k191364/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Automated Platelet Aggregation (JOZ)
Date received	May 22, 2019
Decision date	Feb 14, 2020
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fujimori Kogyo, Co., Ltd.
Location	Shinjuku, Tokyo, JP
Contact	Jeffrey Dahlen
510(k) history	1 submissions · 1 cleared · 2020-2020

CLINICAL EVIDENCE - NCT03621020**Clinical Performance Evaluation of T-TAS 01 PL Chip**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	307 patients (actual)
Study sites	6 sites
Condition studied	Platelet Dysfunction; Von Willebrand Diseases; Healthy; Congenital Platelets Abnormality
Study type	Observational
Completion date	Feb 14, 2020
Sponsor	Hikari Dx, Inc. (Other)

Primary outcome

Sensitivity and specificity for detecting defects in primary hemostasis

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03621020