FDA 510(k) Premarket Notification

K192259 Philips IntelliSite Pathology Solution

CLEARED

Sep 20, 2019
30 days to decision

K192259 · Product code: **PSY** · Pathology
Source: https://www.510kdatabase.net/k192259/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Whole Slide Imaging System (PSY)
Date received	Aug 21, 2019
Decision date	Sep 20, 2019
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Philips Electronics Nederland B.V.**
Location	Eindhover, NL
Contact	Liselotte Kornmann
510(k) history	2 submissions · 2 cleared · 2017-2019