

K203364 MDPC-8127Apr 15, 2021
150 days to decisionK203364 · Product code: **PSY** · Pathology
Source: <https://www.510kdatabase.net/k203364/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Whole Slide Imaging System (PSY)
Date received	Nov 16, 2020
Decision date	Apr 15, 2021
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Barco N.V.
Location	La Jolla, CA, US
Contact	Lieven De Wandel
Website	http://www.barco.com
510(k) history	60 submissions · 60 cleared · 1998-2024

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