

K182263 RetCam 3Sep 7, 2018
17 days to decisionK182263 · Product code: **HKI** · Ophthalmic
Source: <https://www.510kdatabase.net/k182263/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Aug 21, 2018
Decision date	Sep 7, 2018
Days to decision	17 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	RetCam Shuttle ; RetCam Portable

APPLICANT

Company	Natus Medical Incorporated
Location	Oakville, Ontario, CA
Contact	Brian R. Ackley
Website	http://www.natus.com/
510(k) history	10 submissions · 10 cleared · 2010-2018

Natus Medical Incorporated develops diagnostic and monitoring devices for neurological, sensory, and newborn care applications. The company operates with a manufacturing facility in Oakville, Ontario, Canada, and serves healthcare providers globally through neurodiagnostic and sensory screening solutions. Natus Medical received FDA 510(k) clearances from total submissions between 2010 and 2018. The company's cleared devices span General Hospital, Neurology, Ear/Nose/Throat, and Ophthalmic categories, including phototherapy systems, hearing screeners, neurophysiology monit...

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