

K192102 Thermoplastic MasksSep 25, 2019
51 days to decisionK192102 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k192102/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Aug 5, 2019
Decision date	Sep 25, 2019
Days to decision	51 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Aktina Medical Corporation
Location	Congers, NY, US
Contact	Tony Spaccarotella
510(k) history	3 submissions · 3 cleared · 2015-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192102/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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