

K193152 AffinityFeb 14, 2020
93 days to decisionK193152 · Product code: **KPS** · Radiology
Source: <https://www.510kdatabase.net/k193152/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Nov 13, 2019
Decision date	Feb 14, 2020
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hermes Medical Solutions AB
Location	Stockholm, SE
Contact	Joakim Arwidson
510(k) history	16 submissions · 16 cleared · 2012-2025

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