

K202392 SIR-Spheres Microspheres Activity Calculator (SMAC)Oct 23, 2020
63 days to decisionK202392 · Product code: **KPS** · Radiology
Source: <https://www.510kdatabase.net/k202392/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Aug 21, 2020
Decision date	Oct 23, 2020
Days to decision	63 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sirtex Medical US Holdings, Inc.
Location	Woburn, MA, US
Contact	Michael P. Hanley
510(k) history	1 submissions · 1 cleared · 2020-2020

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