

K913641 SOPHY NXTDec 17, 1991
126 days to decisionK913641 · Product code: **KPS** · Radiology
Source: <https://www.510kdatabase.net/k913641/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Aug 13, 1991
Decision date	Dec 17, 1991
Days to decision	126 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Sopha Medical Systems, Inc.
Location	Columbia, MD, US
Contact	RANDY WEATHERHEAD
510(k) history	8 submissions · 8 cleared · 1987-1996

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