

K233530 EXSYS DEXi (EXSYS DEXi-D401S-FRM)

Jul 26, 2024
267 days to decision

K233530 · Product code: **KPR** · Radiology
Source: <https://www.510kdatabase.net/k233530/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Nov 2, 2023
Decision date	Jul 26, 2024
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	EXSYS DEXi (EXSYS DEXi-A401S-FRM); EXSYS DEXi (EXSYS DEXi-D402S-FRM); EXSYS DEXi (EXSYS DEXi-A402S-FRM); EXSYS DEXi (EXSYS DEXi-D401P-FRM); EXSYS DEXi (EXSYS DEXi-A401P-FRM); EXSYS DEXi (EXSYS DEXi-D402P-FRM); EXSYS DEXi (EXSYS DEXi-A402P-FRM); EXSYS DEXi (EXSYS DEXi-D503T-FRM); EXSYS DEXi (EXSYS DEXi-A503T-FRM)

APPLICANT

Company	DRTECH Corporation
Location	Seongam-Si, KR
Contact	Kim Hanbyul
510(k) history	25 submissions · 25 cleared · 2015-2025

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Device record: <https://www.510kdatabase.net/k233530/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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