

510(k) Premarket Notification



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Device Classification Name	system, x-ray, tomography, computed ²²
510(k) Number	K231631
Device Name	BriefCase-Quantification
Applicant	Aidoc Medical, Ltd. 3 Aminadav St. Tel Aviv, IL 6706703
Applicant Contact	Amalia Schreier
Correspondent	Hogan Lovells U.S. LLP 555 Thirteenth Street NW Washington, DC 20004
Correspondent Contact	John J. Smith
Regulation Number	892.1750 ²³
Classification Product Code	JAK ²⁴
Date Received	06/05/2023
Decision Date	11/28/2023
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Radiology
510k Review Panel	Radiology
Summary	Summary ²⁵
Type	Traditional
Reviewed by Third Party	No
Combination Product	No

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