510(k) Premarket Notification

Device Classification Name	automated radiological image processing software[22]
510(k) Number	K232083
Device Name	BriefCase-Quantification
Applicant	Aidoc Medical, Ltd. 3 Aminadav St. Tel Aviv, IL 6706703
Applicant Contact	Amalia Schreier
Correspondent	Hogan & Lovells U.S. LPP 555 Thirteenth Street NW Washington, DC 20004
Correspondent Contact	John J. Smith
Regulation Number	892.2050[23]
Classification Product Code	QIH[24]
Date Received	07/13/2023
Decision Date	11/13/2023
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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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
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