# 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.<br>3 Aminadav St.<br>Tel Aviv, IL 6706703 |
| **Applicant Contact** | Amalia Schreier |
| **Correspondent** | Hogan Lovells U.S. LLP<br>555 Thirteenth Street NW<br>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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25. https://www.accessdata.fda.gov/cdrh_docs/pdf23/K231631.pdf

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