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## 510(k) Premarket Notification



[510\(k\)](#)<sup>7</sup> [DeNovo](#)<sup>8</sup> [Registration & Listing](#)<sup>9</sup> [Adverse Events](#)<sup>10</sup> [Recalls](#)<sup>11</sup> [PMA](#)<sup>12</sup> [HDE](#)<sup>13</sup> [Classification](#)<sup>14</sup> [Standards](#)<sup>15</sup>  
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<b>Device Classification Name</b>	<a href="#">automated radiological image processing software</a> <sup>22</sup>
<b>510(k) Number</b>	K232083
<b>Device Name</b>	BriefCase-Quantification
<b>Applicant</b>	Aidoc Medical, Ltd. 3 Aminadav St. Tel Aviv, IL 6706703
<b>Applicant Contact</b>	Amalia Schreier
<b>Correspondent</b>	Hogan & Lovells U.S. LPP 555 Thirteenth Street NW Washington, DC 20004
<b>Correspondent Contact</b>	John J. Smith
<b>Regulation Number</b>	<a href="#">892.2050</a> <sup>23</sup>
<b>Classification Product Code</b>	<a href="#">QIH</a> <sup>24</sup>
<b>Date Received</b>	07/13/2023
<b>Decision Date</b>	11/13/2023
<b>Decision</b>	Substantially Equivalent (SESE)
<b>Regulation Medical Specialty</b>	Radiology
<b>510k Review Panel</b>	Radiology
<b>Summary</b>	<a href="#">Summary</a> <sup>25</sup>
<b>Type</b>	Traditional
<b>Reviewed by Third Party</b>	No
<b>Combination Product</b>	No

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7. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm>
8. </scripts/cdrh/cfdocs/cfpmn/denovo.cfm>
9. </scripts/cdrh/cfdocs/cfRL/rl.cfm>
10. </scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm>
11. </scripts/cdrh/cfdocs/cfRES/res.cfm>
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13. </scripts/cdrh/cfdocs/cfHDE/hde.cfm>
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15. </scripts/cdrh/cfdocs/cfStandards/search.cfm>
16. </scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm>
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18. </scripts/cdrh/cfdocs/cfAssem/assembler.cfm>
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21. </scripts/cdrh/cfdocs/cfTPLC/tpIc.cfm>
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25. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf23/K232083.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf23/K232083.pdf)

Page Last Updated: 07/08/2024

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14. </scripts/cdrh/cfdocs/cfPCD/classification.cfm>
15. </scripts/cdrh/cfdocs/cfStandards/search.cfm>
16. </scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm>
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