

# K201503 Edge Air(1417) Digital Flat Panel X-ray Detector

Jun 29, 2020  
24 days to decision

K201503 · Product code: **MQB** · Radiology  
Source: <https://www.510kdatabase.net/k201503/>

## SUBMISSION DETAILS

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                         |
| Submission type       | Special  |
| Device classification | Solid State X-ray Imager (flat Panel/digital Imager) (MQB) |
| Date received         | Jun 5, 2020  |
| Decision date         | Jun 29, 2020   |
| Days to decision      | 24 days  |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |

## APPLICANT

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|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Osko, Inc.</b>                     |
| Location       | Miami, FL, US                         |
| Contact        | Richard Jeon                          |
| 510(k) history | 6 submissions · 6 cleared · 2015-2020 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k201503/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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