

**K233968 CINA-iPE**Mar 13, 2024  
89 days to decisionK233968 · Product code: **QAS** · Radiology  
Source: <https://www.510kdatabase.net/k233968/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                                    |
| Submission type       | Traditional   |
| Device classification | Radiological Computer-assisted Triage And Notification Software (QAS) |
| Date received         | Dec 15, 2023  |
| Decision date         | Mar 13, 2024  |
| Days to decision      | 89 days   |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Avicenna.Ai</b>                    |
| Location       | La Ciotat, FR                         |
| Contact        | Stephane Berger                       |
| 510(k) history | 7 submissions · 7 cleared · 2020-2024 |

**REGULATORY CONSULTANT**

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|-----------------|-----------------------------|
| Consulting firm | <b>Hogan Lovells US LLP</b> |
| Contact         | John Smith                  |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233968/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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