

K181964 JiveXOct 23, 2018
92 days to decisionK181964 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k181964/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received | Jul 23, 2018 |
| Decision date | Oct 23, 2018 |
| Days to decision | 92 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Visus Health IT GmbH |
| Location | Bochum, DE |
| Contact | Axel Schreiber |
| 510(k) history | 4 submissions · 4 cleared · 2018-2023 |

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