

K202292 UDEOct 5, 2020
54 days to decisionK202292 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k202292/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received | Aug 12, 2020 |
| Decision date | Oct 5, 2020 |
| Days to decision | 54 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Ebm Technologies, Inc. |
| Location | Taipei, TW |
| Contact | John Su |
| 510(k) history | 1 submissions · 1 cleared · 2020-2020 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202292/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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