

K220727 inHEART MODELSMay 10, 2022
57 days to decisionK220727 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k220727/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received | Mar 14, 2022 |
| Decision date | May 10, 2022 |
| Days to decision | 57 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Inheart, Sas |
| Location | Pessac, FR |
| Contact | Audrey Labèque |
| 510(k) history | 2 submissions · 2 cleared · 2022-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220727/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026