

K222116 Atellica® CI Analyzer, Atellica® IMThyroid Stimulating Hormone 3-Ultra (TSH3-UL), Atellica® CH Albumin BCP (AlbP)Jul 13, 2023
360 days to decisionK222116 · Product code: JLW · Chemistry
Source: <https://www.510kdatabase.net/k222116/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Radioimmunoassay, Thyroid-stimulating Hormone (JLW) |
| Date received | Jul 18, 2022 |
| Decision date | Jul 13, 2023 |
| Days to decision | 360 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Siemens Healthcare Diagnostics, Inc. |
| Location | New York, NY, US |
| Contact | Joy Anoop |
| Website | https://www.siemens-healthineers.com |
| 510(k) history | 152 submissions · 151 cleared · 2008-2026 |

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