

K202852 DiviTum TKaJul 29, 2022
669 days to decisionK202852 · Product code: **QTE** · Immunology
Source: <https://www.510kdatabase.net/k202852/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Thymidine Kinase Activity (QTE) |
| Date received | Sep 28, 2020 |
| Decision date | Jul 29, 2022 |
| Days to decision | 669 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Biovica International AB |
| Location | Uppsala, SE |
| Contact | Joakim Arwidson |
| 510(k) history | 1 submissions · 1 cleared · 2022-2022 |

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