

K231525 VITROS Immunodiagnostic Products CA 19-9TM Reagent Pack

Aug 9, 2023
75 days to decision

K231525 · Product code: **NIG** · Immunology
Source: <https://www.510kdatabase.net/k231525/>

SUBMISSION DETAILS

| | |
|-----------------------|-------------------------------------------------------------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Carbohydrate Antigen (ca19-9), For Monitoring And Management Of Pancreatic Cancer (NIG) |
| Date received | May 26, 2023 |
| Decision date | Aug 9, 2023 |
| Days to decision | 75 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-----------------------------------------|
| Company | Ortho-Clinical Diagnostics |
| Location | Rochester, NY, US |
| Contact | Declan Hynes |
| 510(k) history | 38 submissions · 38 cleared · 1999-2024 |

Ortho-Clinical Diagnostics is an in vitro diagnostics company specializing in clinical laboratory testing and immunohematology. Now part of QuidelOrtho, the brand operates with global research and development centered in Rochester, New York. The company maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions since 1999. Recent clearances span chemistry devices, immunology assays, and microbiology reagents, reflecting the company's focus on diagnostic platforms and assays for disease detection and blood compatibility testing. The V...