

K792524 CK-MB (CREATINE KINASE-MB) RIA CONTROLJan 16, 1980
41 days to decisionK792524 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k792524/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Single (specified) Analyte Controls (assayed And Unassayed) (JJX) |
| Date received | Dec 6, 1979 |
| Decision date | Jan 16, 1980 |
| Days to decision | 41 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Mallinckrodt Critical Care |
| Location | Mchenry, IL, US |
| Website | https://www.mallinckrodt.com |
| 510(k) history | 92 submissions · 92 cleared · 1976-1989 |

Mallinckrodt Critical Care is a medical device manufacturer based in McHenry, US. Now part of Mallinckrodt plc following a 2025 merger and subsequent restructuring, the company maintains a significant historical regulatory record in critical care and specialty medical devices. The company received FDA 510(k) clearances from total submissions between 1976 and 1989. Device clearances span anesthesiology, cardiovascular, gastroenterology, and general hospital categories. Notable cleared products include tracheal tubes, temperature monitoring systems, catheters, and related c...
