

K925880 KODAK AMERLITE CK-MB CONTROL SERA LAN.4413Feb 5, 1993
78 days to decisionK925880 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k925880/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Single (specified) Analyte Controls (assayed And Unassayed) (JJX) |
| Date received | Nov 19, 1992 |
| Decision date | Feb 5, 1993 |
| Days to decision | 78 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Eastman Kodak Company |
| Location | McHenry, IL, US |
| Contact | BRADFORD M SPRING |
| Website | http://www.kodak.com |
| 510(k) history | 238 submissions · 238 cleared · 1977-2006 |

Eastman Kodak Company is a diversified imaging and materials manufacturer headquartered in McHenry, US. The company has a long history in advanced materials, chemicals, and imaging technologies. Eastman Kodak maintains a significant regulatory history in medical imaging devices. The company received FDA 510(k) clearances from total submissions, with clearances spanning from 1977 to 2006. The company's cleared devices focused primarily on radiology and medical imaging systems, including digital radiography systems, picture archiving and communication systems (PACS), and re...
