

K896921 RAICHEM TM HEMOGLOBIN CALIBRATOR

Jan 25, 1990  
45 days to decision

K896921 · Product code: **KRZ** · Hematology  
Source: <https://www.510kdatabase.net/k896921/>

SUBMISSION DETAILS

|                       |                                                            |
|-----------------------|------------------------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)                         |
| Submission type       | Traditional                                                |
| Device classification | Calibrator For Hemoglobin And Hematocrit Measurement (KRZ) |
| Date received         | Dec 11, 1989                                               |
| Decision date         | Jan 25, 1990                                               |
| Days to decision      | 45 days                                                    |
| Third-party review    | No                                                         |
| Combination product   | No                                                         |
| PCCP authorized       | No                                                         |

APPLICANT

|                |                                         |
|----------------|-----------------------------------------|
| Company        | Reagents Applications, Inc.             |
| Location       | Mchenry, IL, US                         |
| Contact        | ELSIE SHRAWDER                          |
| 510(k) history | 63 submissions · 63 cleared · 1980-1998 |