

**K110393 EKF- DIAGNOSTIC HEMO\_CONTROL HEMOGLOBIN MEASUREMENT SYSTEM**Mar 4, 2011  
21 days to decisionK110393 · Product code: **GKR** · Hematology  
Source: <https://www.510kdatabase.net/k110393/>**SUBMISSION DETAILS**

---

|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                           |
| Submission type       | Special  |
| Device classification | System, Hemoglobin, Automated (GKR)                          |
| Date received         | Feb 11, 2011   |
| Decision date         | Mar 4, 2011  |
| Days to decision      | 21 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |
| Other names           | EKF-DIAGNOSTIC HEMOGLOBIN MICROCUVETTES (MODIFIED CURVETTE W |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Ekf Diagnostic GmbH</b>            |
| Location       | Egale, WI, US                         |
| Contact        | STEPHEN GORSKI                        |
| 510(k) history | 5 submissions · 5 cleared · 2003-2020 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k110393/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 15, 2026