

**K881816 ABUSCREEN(R) ONTRAK(TM) FOR BARBITURATES**Jul 28, 1988  
91 days to decisionK881816 · Product code: **DKN** · Toxicology  
Source: <https://www.510kdatabase.net/k881816/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Barbiturate (DKN)
Date received	Apr 28, 1988
Decision date	Jul 28, 1988
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No

**APPLICANT**

---

Company	<b>Roche Diagnostic Systems, Inc.</b>
Location	Mchenry, IL, US
Contact	ADRIENNE CHOMA
510(k) history	296 submissions · 296 cleared · 1983-1999

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k881816/> Data sourced from FDA 510(k) public records (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. - Generated June 23, 2026