

K926198 ACCESS TOTAL BHCG ASSAYFeb 8, 1993
61 days to decisionK926198 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k926198/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Visual, Pregnancy Hcg, Prescription Use (JHI) |
| Date received | Dec 9, 1992 |
| Decision date | Feb 8, 1993 |
| Days to decision | 61 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Bio-Rad Laboratories, Inc. |
| Location | Chaska, MN, US |
| Contact | JAN OLSEN |
| Website | http://www.bio-rad.com |
| 510(k) history | 82 submissions · 82 cleared · 1991-2019 |

Bio-Rad Laboratories, Inc. is an American developer and manufacturer of specialized technological products for life science research and clinical diagnostics. Founded in 1952 in Berkeley, California, the company is based in Hercules, California, with operations worldwide. Bio-Rad has received FDA 510(k) clearances from total submissions between 1991 and 2019. The company's regulatory record reflects a strong focus on chemistry devices, including hemoglobin testing systems, quality control materials, and diagnostic assays. Additional cleared devices span immunology, hemato...
