

K953780 ACCESS ALLERGEN DOG EPITHELIMNov 14, 1995
92 days to decisionK953780 · Product code: **DHB** · Immunology
Source: <https://www.510kdatabase.net/k953780/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Radioallergosorbent (rast) Immunological (DHB) |
| Date received | Aug 14, 1995 |
| Decision date | Nov 14, 1995 |
| Days to decision | 92 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Bio-Rad Laboratories, Inc. |
| Location | Chaska, MN, US |
| Contact | JOAN CHRISTENSON |
| 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...
