

K130053 BIOPLEX 2200 CELIAC IGA AND IGG KITS ON THE BIOPLEX 2200 SYSTEM, BIOPLEX 2200 CELIAC IGA AND IGG CALIBRATOR SETS, AND BISep 19, 2013
247 days to decisionK130053 · Product code: **MVM** · Immunology
Source: <https://www.510kdatabase.net/k130053/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Autoantibodies, Endomysial(tissue Transglutaminase) (MVM)
Date received	Jan 15, 2013
Decision date	Sep 19, 2013
Days to decision	247 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bio-Rad Laboratories, Inc.
Location	Chaska, MN, US
Contact	Juang Wang
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...