

K780114 IMMUNOZYME E. HISTOLYTICA ANTIGENSApr 19, 1978
86 days to decision

K780114 · Microbiology

Source: <https://www.510kdatabase.net/k780114/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Jan 23, 1978
Decision date	Apr 19, 1978
Days to decision	86 days
Third-party review	No

APPLICANT

Company	Millipore Corp.
Location	Mchenry, IL, US
510(k) history	30 submissions · 30 cleared · 1977-2003

Millipore Corp. was a global life science company founded in 1954, based in McHenry, US. Now part of Merck Group, the brand operates under the MilliporeSigma name following Merck's 2010 acquisition and subsequent 2015 merger with Sigma-Aldrich. The company holds FDA 510(k) clearances from total submissions, spanning 1977 to 2003. Millipore specialized in chemistry devices and filtration technologies, with cleared devices across anesthesiology, toxicology, and gastroenterology applications. This regulatory record reflects the company's historical focus on laboratory and cl...