

**K802299 K/K (ASMA/ANA) UNIVERSAL BIOPAK**Jan 29, 1981  
132 days to decisionK802299 · Product code: **DHN** · Immunology  
Source: <https://www.510kdatabase.net/k802299/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN)
Date received	Sep 19, 1980
Decision date	Jan 29, 1981
Days to decision	132 days
Third-party review	No

**APPLICANT**

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Company	<b>Bioware Products</b>
Location	Mchenry, IL, US
510(k) history	4 submissions · 4 cleared · 1980-1981

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