

K831628 CREATININE REAGENTS B6370-13Jul 6, 1983
47 days to decisionK831628 · Product code: **CGX** · Chemistry
Source: <https://www.510kdatabase.net/k831628/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alkaline Picrate, Colorimetry, Creatinine (CGX)
Date received	May 20, 1983
Decision date	Jul 6, 1983
Days to decision	47 days
Third-party review	No

APPLICANT

Company	American Scientific Products
Location	Mchenry, IL, US
510(k) history	28 submissions · 28 cleared · 1981-1986

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Device record: <https://www.510kdatabase.net/k831628/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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