

**K801346 NSI REAGENT SYSTEM FOR ORTHO ELT-8 HEMA**Aug 12, 1980  
64 days to decisionK801346 · Product code: **GIF** · Hematology  
Source: <https://www.510kdatabase.net/k801346/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diluent, Blood Cell (GIF)
Date received	Jun 9, 1980
Decision date	Aug 12, 1980
Days to decision	64 days
Third-party review	No

**APPLICANT**

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Company	<b>Nobel Scientific Industries, Inc.</b>
Location	Mchenry, IL, US
510(k) history	23 submissions · 23 cleared · 1976-1986

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Device record: <https://www.510kdatabase.net/k801346/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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