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Non-Confidential Summary of Safety and Effectiveness

October 17, 1996

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Official contact: Jorge Miller, Director, Coagulation Products

Proprietary or Trade Name: Factor deficient coagulation plasma - V

Common/Usual Name: Qualitative and Quantitative Factor Deficiency Test - V

Classification Name: Qualitative and Quantitative Factor Deficiency Test

Intended device: Factor deficient coagulation plasma - V

Predicate devices: Helena - K792507 - Factor V

Device description: Factor deficient plasma to be free of antigen of Factor V utilized in *in vitro* diagnostic use.

Intended use:

Indicated use - Factor deficient plasma, Factor - V is a human plasma immunodepleted of the specific factor and intended for use in the quantitative determination of the specific factor levels in patients suspected of congenital or acquired deficiency of this specific coagulation protein and is performed by clotting assay.

Environment of use: Clinical laboratories

Comparison to predicate devices:

Attribute	Intended product	Helena
Use		
Indicated for use in determination of coagulation of plasma	Yes	Yes
In vitro diagnostic use	Yes	Yes
Used as a quantitative assay	Yes	Yes
Design		
Factor V deficient plasmas offered	Yes	Yes

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(continued)**

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Comparison to predicate devices: (continued)

Attribute	Intended products	Helena
Packaging either - Frozen or Dry / lyophilized	Yes	Yes
Can be used with different instruments and reagents per manufacturer instructions	Yes	Yes
Materials		
Donor human plasma	Yes	Yes
Various buffers	Yes	Yes
Performance Testing		
Compare assay to known sample	Yes	Yes
Negative by FDA approved test for HIV 1/2 and HBsAG	Yes	Yes
Negative by FDA approved test for HCV and HIV-1ag	Yes	not known
Donor criteria		
Deficiency of relevant factor less than 1%	Yes	not known
Negative for HIV and HBsAG	Yes	Yes
Negative for HCV, HIV-1ag	Yes	not known
No inhibitor present	Yes	not known

Differences

The only difference is that the intended product is claimed to be negative for HCV and HIV-1ag by an FDA approved test.

Any other differences that do exist would not have a significant effect on the safety or effectiveness of the device.