



**UNIVERSAL REAGENTS, INC.**

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OCT 10 1996

K961929

**Non-Confidential Summary of Safety and Effectiveness**

May 15, 1996

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**Official contact:** Jorge Miller, Director, Coagulation Products

**Proprietary or Trade Name:** Factor deficient coagulation plasma - II, V, VII, VIII, IX, X, XI, XII

**Common/Usual Name:** Factor deficient coagulation plasma - II, V, VII, VIII, IX, X, XI, XII

**Classification Name:** Factor deficient coagulation plasma

**Intended device:** Factor deficient coagulation plasma - II, V, VII, VIII, IX, X, XI, XII

**Predicate devices:** Behring Factor Deficient Plasmas -  
K924394 - Factor V, K924396 - Factor VIII, IX, XI, XII  
K924400 - Factor II, VII, X

and

Medical Diagnostics Technologies -  
K893523 - Factor X, K893524 - Factor IX, K893525 - Factor VIII,  
K893533 - Factor V, K893534 - Factor XII, K893535 - Factor VII,  
K893536 - Factor XI, K900133 - Factor II.

**Device description:** Factor deficient plasma to be free of antigen of Factor II, V, VII, VIII, IX, X, XI, XII, respectively, utilized in *in vitro* diagnostic use.

**Intended use:**

Indicated use - Factor deficient plasma, Factor - II, V, VII, VIII, IX, X, XI, XII, 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. Factor VIII is human plasma and bovine material.

Environment of use - Hospital, laboratories

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Comparison to predicate devices: (continued)

Attribute	Intended products	Behring	Medical Diagnostics Technologies
<b>Use</b>			
Indicated for use in determination of coagulation of plasma	Yes	Yes	Yes
In vitro diagnostic use	Yes	Yes	Yes
Used as a quantitative assay	Yes	Yes	Yes
<b>Design</b>			
Factor deficient plasmas offered - II, V, VII, VIII, IX, X, XI, XII	Yes	Yes	Yes
Packaging either - Frozen or Dry / lyophilized	Yes	Yes	Yes
Can be used with different instruments and reagents per manufacturer instructions	Yes	Yes	Yes
<b>Materials</b>			
Donor human plasma	Yes	Yes	Yes
Bovine enhanced factor VIII	Yes	Yes	Yes
Various buffers	Yes	Yes	Yes
<b>Performance Testing</b>			
Compare assay to known sample	Yes	Yes	Yes
Negative by FDA approved test for HIV 1/2 and HBsAG	Yes	Yes	Yes

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**Comparison to predicate devices: (continued)**

<b>Attribute</b>	<b>Intended products</b>	<b>Behring</b>	<b>Medical Diagnostics Technologies</b>
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**Performance Testing (continued)**

Negative by FDA approved test for HCV and HIV-1ag	Yes	not known	not known
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**Donor criteria**

Deficiency of relevant factor less than 1%	Yes	not know	Yes
Negative for HIV and HBsAG	Yes	Yes	Yes
Negative for HCV, HIV-1ag	Yes	not known	not known
No inhibitor present	Yes	not known	Yes

**B. Differences**

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

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