K981174

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510(k) Summary for Cryo✓Check™ Factor XII Deficient Plasma

1. Submitter's Address and Contact Information

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c) Date Prepared: March 10, 1998

2. Device Name

a)	Proprietary (trade) name:	Cryo✓Check™ Factor XII Deficient Plasma
b)	Common name:	Factor 12 Deficient Plasma (human)
c)	Classification name:	Coagulation Factor Deficient Plasma
d)	Classification information:	Regulatory Class II Hematology Panel Product Code - 81 GJT

3. Device Description:

Cryo✓Check™ Factor XII Deficient Plasma is frozen human plasma deficient in the Factor XII coagulation factor. It is prepared from citrated pooled normal human plasma which has been depleted of Factor XII by immunoadsorption. Activity levels of Factor XII are assayed at less than 1% normal levels while all other coagulation factors are greater than 50%.

4. Intended Use

Cryo✓Check™ Factor XII Deficient Plasma is recommended for use as a substrate in clot-based Factor XII assays using the activated partial thromboplastin time (APTT) assay.

5. Substantially Equivalent Device

a) 510(k) number: K900412

b) Trade Name: Factor XII Deficient Plasma

c) Manufacturer: Sigma

d) Substantial Equivalence Comparison

Cryo✓Check™ Factor XII Deficient Plasma is similar to the predicate device in that they both have the same "indications for use"; target population; and are both made from human plasma.

Cryo✓Check™ Factor XII Deficient Plasma differs from the predicate device in that it is a frozen liquid preparation and not a lyophillized product. Additionally, **Cryo✓Check™** Factor XII Deficient Plasma is prepared from normal human plasma from which Factor XII has been immunoadsorbed, while the predicate device is derived from human donors with a congenital Factor XII deficiency.
To our knowledge, these differences do not affect the intended use or performance of the device.

6. Non-Clinical Performance Data - 24 Hour Open Vial Stability :

a) Testing Performed:

i) Factor XII assays were performed on a known reference plasma using vials of **Cryo✓Check™** Factor XII Deficient Plasma as a substrate. Recovered factor XII values were measured at 0 hours and 24 hours. (see table for results)

b) Conclusions:

Test results indicate that a claim of 8 hours open vial stability is acceptable.

Table S1

Open Vial Stability of **Cryo✓Check™**
Factor XII Deficient Plasma

Summary Statistics (% Recovery)

	0 Hours	24 Hours	**Average**
MEAN	92.8	93	92.9
MAXIMUM	96	97	97
MINIMUM	90	89	89
S.D.	2.17	3.16	2.56
2 S.D.	4.34	6.32	5.12
SAMPLE SIZE	5	5	10
C.V.%	2.34	3.4	2.75

Note: Reference Value =
Acceptable values are: Mean (+/-) 5% of reference value; and %C.V. < 5%