510(K) SUMMARY

ZIPThaw™ 202

510(k) Number BK190401

Applicant's Name:

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Trade Name: ***ZIPThaw™ 202***

Summary Preparation Date: **September 17, 2019**

Classification:

Classification name: Blood and plasma warming device
Product Code: KZL
Regulation No: 21 CFR 864.9205
Class: II
Panel: Hematology

Premarket Review: Center for Biologics Evaluation & Research (CBER)

Device Description:

The ***ZipThaw™ 202*** system is a modular thawing plasma device.

It has a small foot-print of controlled thawing of plasma due to a dry heating method and modular architecture platform that provide a two identical chambers basic module. The plasma bag is thawed by the Chamber's heating cushions filled with water-based gel.

The plasma frozen bag is placed inside a ZipSleeve™, a smart overwrap bag and inserted into the Thawing Chamber Module

(**TCM**). During the thawing process, the plasma bag is thawed by the Chamber's heating cushions. The heating cushions temperature are controlled by the system to maintain a heating temperature of 37 °C (98.6 °F).

The plasma frozen bag temperature is monitored by the ZipSleeve™ temperature sensor and will signal the system to stop heating once the sensor temperature reading reaches 33 °C (91.4 °F) while the ***ZipThaw™ 202*** system controls the agitation mechanism to ensure homogeneous mixing and heat distribution.

Indication for Use:

The ***FMS ZipThaw™ 202*** is a thawing device intended for use in blood banks and laboratories for the following applications:

- thawing of Fresh Frozen Plasma (FFP)
- thawing of Plasma Frozen within 24 Hours after Phlebotomy (PF24)

Predicate Devices: Substantial equivalence to the following predicate device is claimed:

	K#	**Company**	**Device Name**	**Clearance Date**
Primary Predicate	BK100051	Boekel	Plasma Thawer Model 301000	April 22, 2011
Reference	BK100063	Barkey	Plasmatherm	November 17, 2011

Comparison with Predicate Devices

The ZipThaw™ 202 primary predicate device is the Boekel Plasma Thawer Model 301000 (510K No. BK100051) since it has the same intended use, clinical indications and implements similar technology.

Both, the ***ZipThaw™ 202*** and the Boekel Plasma Thawer Model 301000 (K100051) are categorized as class II IVD Hematology devices with product code KZL and regulatory

number 21 CFR 864.9205. They are both described as Plasma thawing Devices.

The BK100063 was added as a reference predicate device due to the similarity in the formatting of the clinical indication between the Barkey's Plasmatherm and Fremon Scientific's ***ZipThaw™ 202***.

The ***ZipThaw™ 202*** technology uses two identical chambers basic module. The plasma bag is thawed by the Chamber's heating cushions filled with water-based gel.

The plasma frozen bag temperature is monitored by the ZipSleeve™ temperature sensor and will signal the system to stop heating once the sensor temperature reading reaches 33 °C (91.4 °F) it also stops thawing upon overheating. While the Plasma Thawer Model 301000 technology uses a central water pull that is warmed to 37ºC or to a user preselected value (no temperature sensors).

Performance Standards

The ***ZIPThaw™ 202*** complies with the U.S. code of federal regulation: 21 CFR 864.9205

The ***ZIPThaw™ 202*** complies with the following voluntary standards (Certification for compliance with the following standards follows in section No. 5):

- EN 60601-1-1:2006 + A11 2011 + A1:2013
  IEC 60601-1:2005 (Third Edition + CORR. 1-2006 + CORR. 2:2007 + A1:2012)
  Basic **safety** and essential performance requirements of medical electrical equipment,
- IEC 60601-1-2:2014, 4th edition, Medical electrical equipment electromagnetic compatibility
- IEC 60601-1-6:2010 (Third Edition), AMD1: 2013 "Medical Electrical Equipment - Part 1-6: General requirements for basic safety and essential performance: usability"

Bench Tests

In the table below presented the batch test conducted and their results:

	Parameters	**Results**
Thaw Time	Plasma volume:	Average thawing time (minutes):

	Parameters	Results
	110ml±10ml	8:07 (STD 1:00)
	250ml±10ml	15:51 (STD 1:23)
	450ml±10ml	39:34 (STD 2:49)
ZipSleeve Shelf Life	Accelerated	The accelerated aging results verified that the ZipSleeve qualified for two-year shelf-life
	Real Time	On going
Temperature sensor's accuracy - **ZipSleeve** - **Cushion**	%/^{0}C 1% 1%	 ±0.5°C ±0.5°C
Number of ZipSleeve thawing cycles	Thawing cycles	Max 15 (8 uses is the commercial limit)
Plasma coagulation factors Activity	PT (sec) INR PTT (sec) PROT C (% NP) PROT S (%NP) FVIII (%NP) FV (%NP) VWF ACTIVITY (%NP) TAT(ng/ml)	No more than 20% difference in activity for each factor, between an un-warmed and a warmed unit of fresh frozen plasma (FFP) with 95% Confidence & 95% Reliability and that 95% of pairs meet the criterion.

- Performance bench tests were implemented to show that the ZIPThaw™ 202 is as safe and efficient for performing its intended use as the predicate device.
- Performance of a comparative study to demonstrating that the device does not cause loss of coagulation factor activities in plasma.
  The study included 60 units of FFP and compared the results with the predicate device, Boekel Plasma Thawer Model 301000 (BK100051).
  The frozen 450ml container-bags with 320-380ml plasma were thawed, using ***ZIPThaw™ 202*** and the predicate device. Thawing time and the final temperature were recorded:
  - The average thawing time of the ***ZipThaw™ 202*** is 16.1 min to a temperature of 33.1ºC.
  - The average thawing time of the Boekel 30100 is 20 min to a temperature of 34.2ºC (device has fixed thawing Time).
- The testing results demonstrated that there was no more than **20% difference** in activity for each factor, between an un-warmed and a warmed (by the test device) unit of fresh frozen plasma (FFP) with 95% Confidence & 95% Reliability and that 95% of pairs meet the criterion.
- Eight out of 9 indicators measured have none to minimum number of samples exceeding 20% of the pre-thawing values. There are no statistically significant differences between the pre-thawing group and the two different post-thawing groups.
- Measurements of Thrombin-antithrombin complex (TAT) show that the majority of the samples exceeding 20% of the pre-thawing values. When compared to the pre-thawing samples, there are slight increases in the mean

TAT concentrations in both post-thawing groups, with the Boekel group being statistically significant (p=004). Please note, however, that all TAT values are very low, approaching the lower limit of our ELISA assay (range 1.5-120 ng/ml), and thus the inherent assay error contribute to the apparent differences between pre- and post-thawing samples. More significantly, none of the values exceed the normal human plasma levels of TAT of 1-10 ng/ml, indicating lack of clotting in all samples tested regardless of thawing methods.

Pre-clinical Performance Data

See the table above.

Summary of Clinical Performance Data:

No clinical tests were conducted

Human factors/usability studies

A usability study was implemented as part of the performance tests, to show that the ***ZIPThaw™ 202*** is and showed the device is intuitive and easy to use.

Substantial equivalence conclusion

The performance tests that were conducted show that the ***ZIPThaw™ 202*** meets its intended used and is substantially equivalent to the listed predicate device without raising any new questions of safety and efficacy.