

CYTOTHERM


510K Summary

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Date of Summary	14 April 2008
Trade/Proprietary Name Common Usual Name Classification Name of Device	CytoTherm Plasma Thawing Systems CytoTherm Plasma Thawer, Model CT-D1 Plasma Thawer Class II, 81KZL, 864.9205 Device, Warming. Blood and Plasma
Registration Number	2248707
Legally Marketed Device Under Which Substantial Equivalence is Being Claimed	BK060027 CytoTherm Plasma Thawer Models CT-DR, CT-D4
Device Description.	<p>The CT-D1 is a compact dry plasma thawer for one unit of plasma. Tempered water is recirculated and the temperature of the water maintained in a bladder. Segments of the bladder are pressurized sequentially to massage the plasma bag. The plasma bag is placed between the folds of the bladder.</p> <p>The thawing is controlled by an operator settable digital timer. The display indicates the count down time, the temperature of the water in the bladder and the temperature of the plasma bag itself (with an accessory thermometer).</p>
Intended use.	The CytoTherm plasma thawer is used to thaw one unit of plasma.

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<p>Brief Comparison of Characteristics of the Device Vs. the Legally Marketed Devices</p>	<p>CytoTherm, Trenton, NJ is claiming substantial equivalence of the CytoTherm Plasma Thawing system Model CT-D1 to previously cleared models CT-4T, CT-DR, CT-D4 and CT-D2 under BK060027.</p> <p>The hardware and general construction of the subject 510k model has remained basically the same as the cleared models. The main improvement is that instead of having a large volume water reservoir, like all the previous models, all the water is contained in a small volume, sealed bladder. This substantially shortens the warm-up time required by a factor of 5, from 42 minutes for the CT-DR to 8 minutes. The function and programming of the subject model remains the same as the previous cleared devices.</p>
<p>Brief Discussion of Testing And Results Submitted In Application</p>	<p>In house testing on the Model CT-D1 yielded satisfactory thawing times. Since we cannot acquire frozen plasma, we froze 250 ml of water in 300 ml bags for 48 hours at -22 deg C. The water temperature for all thawing is 37.0 +/- 0.1 deg C. When the solution is all liquid without any slivers of ice, it is considered thawed. The model CT-D1 was brought up to temperature (37 deg C) and a frozen "plasma" bag was installed. The thawing was time averaged 21 minutes, which added to the warm-up time of 8 minutes yielded a total of 29 minutes from starting with the CT-D1 at room temperature to having a thawed plasma bag ready for a patient.</p>
<p>Conclusions Drawn from the Testing that Demonstrate The Device is Safe, Effective, And Performs As Well As or Better than the Legally Marketed Device.</p>	<p>The CT-D1 is a very compact dry plasma thawer, that thaws plasma efficiently. Because it is dry it is less likely to compromise sterility. There is no need to wipe off the plasma bags and leave wet towels and wet gloves to possibly breed bacteria.</p> <p>It should be an ideal plasma thawer for a small clinic where plasma is thawed occasionally. Because of the very short warm-up time it does not have to be turned on continuously.</p>


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