

# CYTOTHERM

## 510K Summary

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| Date of Summary  | 28 July 2006   |
| Trade/Proprietary Name<br>Common/Usual Name<br>Classification Name of Device       | CytoTherm Plasma Thawing Systems<br>CytoTherm Plasma Thawer<br>Plasma Thawer<br>Class II, 81KZL, 864.9205<br>Device, Warming. Blood and Plasma   |
| Registration Number  | 2248707  |
| Legally Marketed Device<br>Under Which Substantial<br>Equivalence is Being Claimed | BK960012 CytoTherm S Plasma Thawer<br>K812311 Circulating CytoTherm<br>K813489 Rocking/Circulating CytoTherm   |
| Device Description   | CytoTherm Plasma Thawing Systems are tabletop plasma thawing/warming devices used to thaw frozen plasma bags in hospitals or lab blood bank settings, including trauma centers. Wet and dry models for small |

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and large volume thawing are available. These systems (models) are similar in design and function to the model CT-S and the model CT-II and CT-X, which were the subjects of Premarket Notifications K812311, K813489 and BK960012 respectively.

## Intended Use of the Device(s):

The CytoTherm Plasma Thawing Systems are intended for use in blood banks and labs for warming previously frozen plasma. The larger model is intended for high volume labs and trauma centers. Previously collected plasma is quickly thawed in any one of our systems. Both wet and dry thawing models are available.

## Brief Comparison of Characteristics of the Devices Vs. the Legally Marketed Devices

CytoTherm, Trenton, NJ is claiming substantial equivalence of the CytoTherm Plasma Thawing Systems Models CT-DR, CT-D4, CT-4T and CT-D2 to previously cleared models CT-X (K812311), CT-II (K813489) and CT-S (BK960012). All the subsequent models are further improvements on the cleared models.

Model CT-4T is a deeper version of the rocking CT-II to accommodate larger plasma bags.

Model CT-DR is like the model CT-II but with "inverted" overwrap bags (bladders). The plasma bag and gloved hands remain dry. This is a more sterile and convenient way to thaw.

Model CT-D4 is a further improved model that eliminates the mechanical rocking of the model CT-DR and uses 2 pumps to pressurize different chambers of the inverted overwrap bag (bladder) to massage the plasma in its bag to speed thawing.

The Model CT-D2 is a smaller version of the CT-D4.

The Model CT-4S is a slightly larger version of the sliding action CT-S.

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The hardware and general construction of the subject 510k models has remained basically the same as the cleared models. The CT-D4 and CT-D2 have a second magnetic pump to massage the plasma bags. The function and programming of the subject models remains the same as previously cleared devices. We have updated the software, including digital controls, for end user convenience.

## Brief Discussion of Testing And Results Submitted In Application:

In house testing on all subject models yielded satisfactory thawing times, acceptable to laboratory standards. Since we cannot acquire plasma, we froze 250 ml of water in 300 ml bags for 48 hours at -22 deg C. Test parameters: All units were frozen at -22 deg C for at least 48 hours. Bath temperature for all thawing is 37.0 +/- 0.1 deg C. Use 250 ml of solution in a 300 ml bag in all tests except where noted. When the solution is all liquid without any slivers of ice, it is thawed. Each model was brought up to temperature (37 deg C) and a frozen "plasma" bag was installed. The thawing was timed, ranging from 12 minutes on the model CT-4S to 16 minutes on the CT-DR. The results were recorded.

Conclusions Drawn from the  
Testing that Demonstrate  
The Device is Safe, Effective,  
And Performs As Well As or  
Better than the Legally Marketed  
Device

In house testing and actual laboratory testing has shown that the subject models thaw at the same rate than previously approved models. With technology advancing over the years and customer feedback, we have taken the initiative to supply the market with safe and reliable plasma thawers, utilizing the most advanced technology available. Because of customer suggestions, we have several models available both wet and dry. The wet models can thaw between 1 and 12 plasma bags. The dry models can thaw between 1 and 6 plasma bags.

  
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