

510(k) Summary

The following information is provided in accordance with 21 CFR 807.92, for the Premarket 510(k) summary:

(1) SUBMITTER INFORMATION

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Date Prepared: June 21, 2019

(2) NAME OF THE DEVICE

Trade Name: Timestrip® Blood Temp 10 (BT10)

Common Name: Nonreversible Temperature Indicator

Classification Name: Supplies, Blood-Bank

(3) PREDICATE DEVICE

Trade Name: Timestrip® Blood Temp 10 (BT10)

Common Name: Nonreversible Temperature Indicator

Classification Name: Supplies, Blood-Bank

510(k) Number: BK150289

Decision Date: 12/14/2015

(4) DEVICE DESCRIPTION

The Timestrip® Blood Temp 10 (BT10) is a single use temperature-sensitive indicator in a self-adhesive label format that is designed to be applied directly to a blood bag and will display a color change to alert when blood exceeds a certain temperature. The indicator is designed to correlate with the core temperature of blood in a blood bag and changes color if the core temperature has reached or exceeded 10°C/50°F. The indicator itself is inert so it can be transported and stored at room temperature and is activated prior to use by squeezing an activation button firmly between a thumb and finger.

The principal of operation is a blue liquid dye housed in a blister is held adjacent to a micro-porous membrane. Upon squeezing the activation button, the dye comes out of the blister and into contact with the membrane and the indicator arming window changes from yellow to green. As soon as the indicator is adhered to the chilled blood bag, the liquid dye solidifies. If the temperature of the product is below the stated 'STOP' temperature of 8°C/46°F, the liquid turns solid and in this state is unable to move through the membrane. If the temperature rises to or above the threshold temperature of 10°C/50°F, the dye changes to liquid form, moves through the membrane and the color in the white breach window changes from white to blue.

The arming/activation window gives an immediate confirmation that the indicator is armed as it turns from yellow to green. The breach/indication window is separate so it can be clearly seen if there has been a breach of the 10°C/50°F temperature threshold. If no breach has occurred the window will remain white. Any blue coloration of the breach/indication window (partial or full) denotes a temperature breach of the 10°C threshold.

The difference between this device and the previous version (BK150289) is the use of a new adhesive. (b) (4) will now be used instead of the (b) (4) adhesive.

(5) INTENDED USE

The Timestrip® Blood Temp 10 (BT10) blood bag indicator is a temperature – sensitive indicator that can be used by blood banks and transfusion services to maintain quality control in blood storage and transportation. The intended use of the modified device has not changed as a result of the modifications.

(6) COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Timestrip® Blood Temp Indicator and the predicate device operate using the same technological principles. Both devices have the same descriptive characteristics in that they employ a temperature sensitive sticker placed on a blood bag to indicate if there is a change to the core temperature of the blood. Both devices have the same indications

for use as they are used by blood banks and transfusion services to maintain quality control in blood storage and transportation.

(7) PERFORMANCE DATA

Summary of Performance Testing

Timestrip conducted adhesion validation testing of the new Timestrip® Blood Temp 10 device. This test was performed to validate BT10 adherence stability. Storage of activated BT10 on blood-bag inside a refrigerator did not affect the adherence properties after all periods of 5, 15 and 40 days. The BT10 also underwent a transportation stability test. A pass is considered if BT10 devices still adhere to the blood bag. These are observed through visual inspection. All tested products passed the adhesion validation test.

Test Performed	Device Description/Sample Size	Test Method	Acceptance Criteria	Results
Adhesive Validation Report – Blood Temp 10	48 BT10 Devices	Visual Inspection of Adhesion over time Visual inspection of adhesion after transportation simulation	Visual inspection of adherence of BT10 to blood bag	Pass

The Adhesion Validation Report is provided in **Attachment 2**

Summary of Animal Studies

No animal testing was necessary.

Summary of Clinical Studies

No clinical testing was necessary.

Substantial Equivalence

The new Timestrip® Blood Temp Indicator and the previous version (BK150289) have the same technological characteristics and intended use. The new Timestrip® Blood Temp Indicator does not raise new questions of safety or effectiveness to the predicate device cleared under BK150289. This is reflected in following substantial equivalence criteria:

- Design: Both devices employ a temperature sensitive sticker placed on a blood bag to indicate if there is a change to the core temperature of the blood
- Specifications: Both devices indicate a breach if the blood bag temperature approaches 10°C.

- Mechanism of Action: Both indicators utilize phase change from solid to liquid to indicate a temperature breach. Both indicators display a color change on the top of the device to indicate when the core temperature approaches a breach.
- Both devices have a plastic housing, with the same materials used
- Both devices are the same size.

Minor differences in design characteristics do not raise issues of substantial equivalence of the modified Timestrip® Blood Temp 10 (BT10). Therefore, Timestrip believes that the modified Timestrip® Blood Temp 10 (BT10) is substantially equivalent to the existing legally marketed predicate device.