October 19, 2015

VIA FACSIMILE AND UPS

Timestrip UK, Ltd.
Trinity House
Cambridge Business Park
Cambridge, CB4 0WZ

Dear Timestrip UK:

The Food and Drug Administration (FDA) has reviewed your Internet website: http://timestrip.com/products/blood-range/. Your website states that the Timestrip Blood Temp 10 – Nonreversible Temperature Indicator (Blood Temp 10), is "…a single use temperature indicator in a self-adhesive label format. It has been engineered for use on blood bags. It indicates if the core temperature of blood in a blood bag has reached or exceeded 10°C/50°F."

Blood Temp 10 is a medical device within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) in part because it is an instrument, apparatus, implement, machine, contrivance, implant, in vitro agent, or other similar or related article, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or function of the body of man or other animals (21 U.S.C. § 321(h)).

Your Internet website describes the device as being used by clinicians to ensure that blood and blood products intended for transfusion have been stored under the appropriate temperature conditions and are safe for human use. Your Internet website makes claims such as:

- "With the push of a button the Timestrip Blood Temp 10 makes it possible to reissue blood which would otherwise be discarded."
- "Timestrip Blood Temp 10 ensures bacteria growth due to elevated temperatures has not compromised blood during storage, transportation, and distribution."
- "The Timestrip Blood temp 10 provides auditable proof that your blood has been stored, transported, and reissued properly and according to relevant regulatory standards."

The Act requires that manufacturers of medical devices obtain marketing approval or clearance for their products from the FDA before they may offer them for sale in the United States. This helps protect the public health by ensuring that medical devices are safe and effective or substantially equivalent to other devices already legally marketed in the United States.

A review of our databases disclosed that your firm has not obtained premarket approval or clearance for this device in the United States and has not received an investigational device exemption from premarket approval either. Nevertheless, the Internet website above offers the sale of Blood Temp 10 to buyers in the United States. This devices is being sold in the United States by at least three distributors (copied on this letter). Because you do not have marketing

approval or clearance from FDA, marketing this product in the United States is in violation of the Act.

For the above reasons, the Blood Temp 10 device is adulterated under section 501(f)(1)(B) of the Act,. 21 U.S.C. 351(f)(1)(B), because you do not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. 360j(g). Additionally, the device is misbranded under section 502(o) the Act, 21 U.S.C. 352(o), because notice or other information respecting the device was not provided to FDA, as required by section 510(k) of the Act, 21 U.S.C. 360(k).

If you have any questions regarding this matter, you may contact.LT Shannon Aldrich, Regulatory Reviewer, Division of Case Management, Office of Compliance and Biologics Quality at (240) 402-8876. Please be advised that only written communications are considered official.

Sincerely,

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

cc: (b) (4)

Genesis BPS
465 Route 17 South
Ramsey, New Jersey 07446

(b) (4)