Harpera Microbiopsy Tool (IUO): Safety Statement

Harpera Device Description and Intended Use

Trajan Harpera (IUO) is a medical device currently under development for the collection of a microbiopsy from skin, for use in clinical studies. In the hands of a trained healthcare professional, this minimally invasive device utilizes a novel technique to collect skin biopsy specimens, including from sensitive areas around the face. This single-use device is supplied individually wrapped and has been exposed to a gamma irradiation process similar to processes utilized for the sterilization of other surgical instruments. Harpera is not associated with any specific diagnostic test or testing scheme and is not intended for the analyses of a specific disease states.

Data From Clinical Studies

Several clinical studies have been conducted by Trajan collaborators using Harpera prototype devices. No adverse events were reported to Trajan and no field safety corrective actions (FSCA) were requested during the course of these studies.

Several studies investigated subjects' pain response during the biopsy process utilizing Harpera. A pain score was recorded and the results indicate that study subjects did not experience significant pain during the procedure [*Lin et al. (2013), Churiso et al. (2020), Yamada et al. (2020)].*

Currently, a Human Factor Engineering study is being planned to evaluate the safety parameters for the use of Harpera. Included will be a survey to determine ease-of-use of the device as well as comprehension of the instructions for use (IFU).

Regulatory Status

Harpera is a Development Stage Device and is supplied as "Investigational Use Only" (IUO) for clinical studies, with appropriate labeling. Validation of the design, performance and safety of the device has not been completed.

Stability of a Harpera skin specimen has been investigated through genomic techniques (i.e. detection of common housekeeping RNA, human DNA). However, validation of specimen stability for specific biomarkers is beyond the intended purpose of the device.

Trajan plans to initiate the regulatory filings in several jurisdictions in 2024.

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Global Head, Regulatory Affairs.

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