August 28, 2019

Cryos Technologies Inc.
% Louis-Paul Martin
President
LOK North America Inc.
2025 rue Michelin
Laval, CA
H7L 5B7 Quebec

Re: K183485
Trade/Device Name: CryoVizion System
Regulatory Class: Unclassified
Product Code: LDK
Dated: July 26, 2019
Received: July 30, 2019

Dear Louis-Paul Martin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek Pinto, Ph.D.
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183485

Device Name
CryoVizion System

Indications for Use *(Describe)*
The CryoVizion is indicated as a tool to quantify angles on digital photograph depictions such as body angles related to postural asymmetries. It is intended for use in professional health care facilities by health specialists such as podiatrists, orthopedist, physiotherapists, chiropractors, osteopaths, and kinesiotherapists

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

1. **Type of Submission** — Traditional

2. **Preparation Date** — August 23rd, 2019

3. **Submitter Address**

Cryos Technologies Inc.
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J6E 4G4
Phone: 1 (450) 753-3704
Contact: John Stimpson, President

4. **Contact Person**

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5. Identification of the Device

Proprietary Name/Trade Name	CryoVizion System
Regulation Description	Device, Sensing, Optical Contour
Device Classification	Unclassified (Pre-Amendment)
Regulation Number	n/a
Panel	Physical Medicine
Product Code	LDK

6. Identification of the Predicate

Predicate Device Name: Quantec Spinal Measurement System

510(k) Number: K923792

7. Intended Use and Indication for Use

The CryoVizion is indicated as a tool to quantify angles on digital photograph depictions such as body angles related to postural asymmetries. It is intended for use in professional health care facilities by health specialists such as podiatrists, orthopedist, physiotherapists, chiropractors, osteopaths, and kinesiotherapists.

8. Device Description

The CryoVizion System is a non-invasive and radiation-free system.

Patients, suitably undressed, are placed in an observation booth. Two digital colour cameras mounted on a column are placed facing the patient booth. Patients are illuminated by two LED lighting units—one on each side of the imaging column. Using the CryoVizion System, the health specialist can then take images of the patient at various heights and in different positions. These images are then saved in the patient's file.

The health specialists can then visually review anatomical and morphological features related to the patient's posture. To do this, the CryoVizion System provides an image analysis toolbox including a palette of six graphic filters.

Surface markers corresponding to the anatomical body landmarks placed using palpation by healthcare professionals, prior to taking the photographs, may also be used to help identify and reference anatomical landmarks in the photographs.

The CryoVizion System is composed of two sections: hardware and software. The data and the images collected with the CryoVizion System are available immediately for clinical use and may be downloaded to a computer for storage or further analysis or comparison.

The hardware section comprises the above noted two digital colour cameras and two LED lighting units, mounted on a column and a positioning booth. The two cameras are mounted in the central tube of the imaging column. The LED lighting systems are vertically disposed to each side of the column. The column also houses the control centre which, linked to a computer, controls the two digital cameras and the intensity of the lighting.

The software comprises image manipulation functions, including the user selectable filters noted above and controls to operate each of the cameras.

9. Performance Data

The following performance data were provided in support of the substantial equivalence determination:

Electrical safety and electromagnetic compatibility (EMC)

The CryoVizion System complies with the following recognized standards:

- IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance;
- IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests; and
- IEC 60601-1-6 Medical electrical equipment – Part 1-6: General requirements for safety – Collateral safety: Usability.

Angle Measurement Accuracy and Single Tester's Measurement Repeatability

- The system angle measurement functionality was verified for accuracy by comparing its output relative to that of a manual goniometer which is a "*gold standard*" method currently used for body segment angle measurements.
- This included two variance analysis (ANOVA) studies to assess intra and inter user accuracy variability, as well as a bias and linearity study of the variability of repeated measurements, both as compared to goniometer measurements.

Software Verification and Validation Testing

The software validation activities were performed in accordance with IEC 62304:2006- Medical device software – Software life cycle processes, in addition to the FDA Guidance documents, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical* Devices" and "*Content of Premarket Submission for Management of Cybersecurity in Medical Devices*."

Animal Study

The 510(k) does not contain animal study test results for the subject device.

Clinical Studies

A clinical study specific to the CryoVizion System complemented by information from clinical studies selected within the literature and concerned about the reproducibility and reliability of photogrammetry was provided as valid scientific evidence to demonstrate that the CryoVizion System is safe and effective for its intended use, substantially equivalent to the currently cleared predicate device (K923792), and raises no new questions of safety and effectiveness.

10. General Safety and Effectiveness Concerns

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device. Risk Management is ensured and documented in compliance with ISO 14971 to identify and provide mitigation to potential hazards. To minimize risks, Cryos Technologies adheres to recognized and established industry practices and standards. Furthermore, the operators are healthcare professionals familiar with and responsible for the evaluation and postprocessing of the surface topography images.

11. Substantial Equivalence Determination

The overall technological comparisons, based upon the results of a literature search, between the subject device and the predicate, are summarized in the following table:

Items	**Predicate Device** Quantec Spinal Measurement System (K923792)	**Subject Device** CryoVizion System (K183485)
Classification	Unclassified	Unclassified
Code of Federal Regulations	Unclassified	Unclassified
Product Code	LDK	LDK
Classification Name	Device, Sensing, Optical Contour	Device, Sensing, Optical Contour
Prescription Medical Devices	Yes	Yes

Intended Use / Indication for Use	Indicated as an optical contour sensing device to provide topographical images for the 3D assessment of back asymmetries.	The CryoVizion is indicated as a tool to quantify angles on digital photograph depictions such as body angles related to postural asymmetries. It is intended for use in professional health care facilities by health specialists such as podiatrists, orthopedist, physiotherapists, chiropractors, osteopaths, and kinesiotherapists.
Populations	Adult or pediatric populations	Adult or pediatric populations
Intended Users	Health specialists such as podiatrists, pedorthists, orthopedist, physiotherapists, chiropractors, osteopaths, and kinesiotherapists.	Health specialists such as podiatrists, pedorthists, orthopedist, physiotherapists, chiropractors, osteopaths, and kinesiotherapists.
Environment	Health care facilities	Health care facilities
Technique	Surface Topography - structured light projection	Surface Topography - structured light projection
Method	Non-Tactile	Non-Tactile
Measurement	Static	Static
Principle of Operation	Based upon raster stereography/ photogrammetry	Based upon digital photogrammetry
Hardware Component	• Digital Camera; • Quartz halogen light; and • Booth	• Digital Camera; • LED • Booth
Software	Software to control the camera, measure the 3D trunk images and to record and quantify deformities (3D assessment)	Software to control the camera, filter pictures for analysis, perform angular measurements of user selected features, and record the images and results.
Use of Body Markers	Yes	Yes
Components	- Digital camera - Software - Quartz halogen light - Booth	- Digital camera - Software - LED - Booth

The general intended use and technology are equivalent between the predicate and the CryoVizion. The main difference is that the predicate outputs 3D surface models of the patient's trunk and quantifies related alignment and deformity parameters corresponding to given anatomical markers placed by the user, whereas in comparison the CryoVizion provides 2D images of the patient's body areas of interest with image filters adjusted by the user to help the user identify asymmetries along with the use of markers in order to help assess deviations and deformities in body segments.

The method was found to be appropriate and reproducible for its intended use per a clinical study and other clinically available data in the literature.

12. Performance Specifications

The following performance specifications were determined specific to the proposed device to establish its safety and effectiveness were evaluated and found to be met:

- Biocompatibility
- Electrical, including Usability
- EMC/EMI Safety
- Software

13. Conclusion

The information provided by Cryos Technologies in this submission demonstrate that the subject device, the CryoVizion System, is safe and effective for its intended use, substantially equivalent to the currently cleared predicate device (K923792) and raises no new questions of safety and effectiveness.