September 20, 2019

Epica International Inc.
% Frank Pokrop
Consultant (510K)
Frank Pokrop
3577 Sand Court
CARLSBAD, CA 92010

Re: K190856
Trade/Device Name: SeeFactorCT3
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS
Dated: April 10, 2019
Received: April 15, 2019

Dear Frank Pokrop:

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,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*

K190856

Device Name

SeeFactorCT3

Indications for Use *(Describe)*

SeeFactorCT3 is a cone beam computed tomography x-ray imaging system that acquires sequences of the head including the ear, nose and throat (ENT), dento-maxillofacial complex, teeth, mandible and jaw, temporo-mandibular joint (TMJ), other areas of human skull and neck with sections of upper cervical spine, and upper and lower extremities for use in diagnostic support. The device displays two and three dimensional images for each examined anatomical region.

The device is operated and used by physicians, dentists, x-ray technologists and other legally qualified professionals.

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

5.1 Applicant/Submitter

Company Name	:	Epica International Inc.
Establishment Registration Number	:	
Phone Number	:	1-425-941-7365
Company Street Address	:	2753 Camino Capistrano. Suite A-101
Fax Number	:	(949) 238-6322
City	:	San Clemente
State	:	CA
Country	:	USA
Zip Code	:	92672

5.2 Contact Person

Full Name	:	Frank Pokrop
Job Title	:	Consultant (510(k))
Phone	:	1-442-273-4827
Email	:	pokropf53@outlook.com

5.3 Date of Preparation

Date of Preparation	:	03/29/2019

5.4 Device Information

Table - Device Information

Trade Name	SeeFactorCT3
Common or Usual Name	Computed tomography x-ray system.
Classfication Name	21 CFR 892.1750
Regulatory Class	2
Product Code	OAS

5.5 Predicate Device(s)

Table - Predicate Device(s)

Predicate Type	510(k) Number	Device Name	Manufacturer
Primary Device	K142222	NewTom 5G	THEMA S.r.l. (Italy)
Reference Device	K130442	NewvTom VG i and] NewTomn 5G	THEMA S.r.l. (Italy)

5.6 Device Description

See Factor CT3 is a Diagnostic CBCT (Cone Beam Computed Tomography) device that integrates High Definition Computed Tomography (HDCT) for obtaining High Resolution 3D Volume with 2D High Resolution Scouting, through Dynamic Scouting and Single Pulse Modality.

5.7 Intended Use/Indications for Use

SeeFactorCT3 is a cone beam computed tomography x-ray imaging system that acquires sequences of the head including the ear, nose and throat (ENT), dento-maxillofacial complex, teeth, mandible and jaw, temporo-mandibular joint (TMJ), other areas of human skull and neck with sections of upper cervical spine, and upper and lower extremities for use in diagnostic support. The device displays two and three dimensional images for each examined anatomical region.

The device is operated and used by physicians, dentists, x-ray technologists and other legally qualified professionals.

5.8 Comparison of Technological Characteristics with Predicate

See **Appendix #1** for a detailed comparsion of the proposed device and the predicate device.

Method of Preformance and Operation :

Both the proposed device and the predicate device utilize the same type of energy and the same type of methodology for obtaining diagnostics imaging: cone-beam computed tomography x-ray imaging.

5.9 Performace Data

Non Clinical :

Living and deceased animals were imaged during the development of this device. A substantial number of diagnostic-quality animal images are shown in the appendices. **See Appendices 2, 3 and 4.**

5.10 Biocompatibility Testing

Biocompatibility testing for patient contact materials wsa not performed due to the limited period of patient exposure which typically occurs at lengthy intervals. The factory statement is attached here.

5.11 Clinical Testing

No clinical testing was performed in the development of this product. A substantial number of diagnostic-quality animal images are shown the appendices.

5.12 Conclusion

The proposed device operates the same as the predicate device using the same source of power, the same method of image acquisition, the same intended use, the same indications for use and both are targeted towards the same group of professional healthcare workers.

The proposed device while identical in many ways and similar in a some others, does have superior imaging resolution, it weighs less, it can be moved and it can be covered during surgical procedures - should there be a need.