



Food and Drug Administration
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CAScination AG
% Mr. Matthias Peterehans
CEO
Steigerhubelstrasse 3
CH-3008 Bern
SWITZERLAND

January 20, 2016

Re: K152473
Trade/Device Name: CAS-One IR
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: November 20, 2015
Received: November 27, 2015

Dear Mr. Peterehans:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152473

Device Name

CAS-One IR

Indications for Use (Describe)

CAS-One IR is a user controlled, stereotactic accessory intended to assist in planning, navigation and manual advancement of one or more instruments, as well as in verification of instrument position and performance during Computed Tomography (CT) guided procedures.

In planning, the desired needle configuration and performance is defined relative to the target anatomy.

In navigation, the instrument position is displayed relative to the patient and guidance for needle alignment is provided while respiratory levels are monitored.

In verification, the achieved instrument configuration and performance are displayed relative to the previously defined plan through an overlay of the pre- and post- treatment image data.

CAS-One IR is indicated for use with rigid straight instruments such as needles and probes used in CT guided interventional procedures performed by physicians trained for CT procedures.

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.

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5: 510(k) Summary

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510(k) Summary

Manufacturer: CAScination AG
Contact: Matthias Peterhans
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Tel: +41 31 552 0440
Date Prepared: 12 January 2016
Trade Name: CAS-One IR
Common Name: Navigated system for CT guided interventions
Classification Number: 21 CFR 892.1750, Computed Tomography X-Ray system
Product Code: JAK, System, X-ray, Tomography, Computed
Predicate device(s): ig4 Image Guided System [K060903] (JAK, 21 CFR 892.1750)
MAXIO [K132108] (JAK, 21 CFR 892.1750)

Intended Use:

CAS-One IR is a user controlled, stereotactic accessory intended to assist in planning, navigation and manual advancement of one or more instruments, as well as in verification of instrument position and performance during Computed Tomography (CT) guided procedures.

In planning, the desired needle configuration and performance is defined relative to the target anatomy.

In navigation, the instrument position is displayed relative to the patient and guidance for needle alignment is provided while respiratory levels are monitored.

In verification, the achieved instrument configuration and performance are displayed relative to the previously defined plan through an overlay of the pre- and post- treatment image data.

CAS-One IR is indicated for use with rigid straight instruments such as needles and probes used in CT guided interventional procedures performed by physicians trained for CT procedures.

Description:

The system consists of three main components:

- A mobile navigation platform: this platform can be moved in and out of radiology rooms and is positioned next to the patient in front of the CT scanner. The platform includes two touch screens, a camera and a computer.
- Aiming device with trackable aiming insert: To aim the needles to their correct locations, the system uses an aiming device. The aiming device is attached to a multi-axis mechanical arm that can align the position of the aiming device around the expected needle entry position. The aiming device is first aligned to the desired entry point (translational alignment) and then alignment to the desired needle insertion angle is performed using a remote center of rotation principle (rotational alignment). There are two possible configurations of the aiming device.

- Instrument adapter clamp with trackable marker shield: As an alternative to the aiming device, trackable markershields can be attached directly to rigid needles by means of an instrument adapter. Calibration of the needle geometry is performed with a calibration unit supplied by CAScination.
- CAS-One IR software: The software provides the step-by-step workflow assistance for needle navigation. It provides a means for users to precisely plan a single or multiple needle trajectories, navigate a needle to this exact position and validate the inserted needle's position to the planned position.

Substantial Equivalence:

CAS-One IR has been shown to be equivalent to:

- MAXIO (Perfint Healthcare, Pvt. Ltd.) [K132108]
- ig4 Image Guided System (Veran Medical Technologies) [K060903]

CAS-One IR was compared and evaluated to the predicate devices with respect to the following characteristics:

- Planning
- Needle configuration and performance
- Navigation
- Respiratory motion control
- Intra-interventional verification
- Post treatment verification
- Interventional instruments
- User
- Imaging modality

The above characteristics were evaluated and found to have the same intended use as the predicate devices. Where technological differences were identified, performance data was supplied to support the conclusion that CAS-One IR does not raise different questions of safety and effectiveness.

CAS-One IR is shown to be substantially equivalent to the predicate devices.

Biocompatibility

All devices of CAS-One IR have the following patient contacting characteristics:

- Surface Devices
- Skin
- Limited (<24h)

These components were assessed for their biocompatibility through their adherence to material standards and appropriate testing according to ISO 10993.

Electrical Safety

Electrical safety tests according to IEC 60601-1:2005/A1 2012 and IEC 60601-1-2:2007 were conducted on CAS-One IR and the system was found to conform.

Software Verification and Validation

Through risk management, the software was classified as having a moderate level of concern as a latent flaw in the software could result in minor injury to the patient. Verification and validation testing appropriate to the software classification was carried out.

Performance Data

A positional accuracy bench test was conducted between the real-time tracking system used in the predicate device and CAS-One IR to show that the two technologies were substantially equivalent.

Performance of the patient registration method was evaluated and shown to be a safe and effective method of registering.

The integrated clinical workflow was benchmarked against the predicate devices and CAS-One IR was shown to be safe and effective.

An accuracy test that evaluated all needle insertion configurations of CAS-One IR was conducted on a phantom within the context of clinical use and each method was shown to be accurate and as safe and effective as the predicate devices.

A post-clinical evaluation of interventions conducted with CAS-One IR showed the system to be accurate and as safe and effective on patients within a clinical context as the predicate devices.

Usability studies with qualified users of varying degrees of experience was conducted and analysed in terms of both risk management and human factors. CAS-One IR was shown to be easy and accurate to use for both novice and experienced users.

Conclusion

The above performance testing and substantial equivalence to predicate devices shows that CAS-One IR is safe and effective for its intended use.