K073074

# 510(k) Summary

DEC 19 2008

This 510(k) summary is prepared in accordance with 21 CFR 807.92.

## General Information

| | |
|---|---|
| Trade Name | ***CT Brain Perfusion for Ziostation*** |
| Common Name | Brain Perfusion Software Tool |
| Classification Name | System, Image Processing, Radiological (21 CFR § 892.2050 - LLZ) |


Applicant: Ziosoft, Inc.
2200 Bridge Parkway, Ste. 103
Redwood City, CA 94065
Tel 650-413-1300
Fax 650-596-7319

Contact: Richard Ball
Director, Regulatory and Quality Affairs


## Intended Use

Ziostation is an image processing workstation software package designed to run on standard PC hardware. It provides for the viewing, quantification, manipulation, communication, printing, and management of medical images. It is intended for use by trained medical professionals to aid in their reading and review of such data. In addition, Ziostation has the following indication:

The CT Brain Perfusion for Ziostation option is an image analysis software package providing additional image processing capabilities to the basic Ziostation device. The CT Brain Perfusion Option is intended for post-processing based on dynamic CT images continuously acquired during the injection of contrast, for the visualization of apparent blood flow in brain tissue and pictorial illustration of perfusion-related parameters to aid in the assessment of the type and extent of cerebral perfusion disturbances.

## Predicate Device

| Manufacturer | Device Name | 510(k) Number |
|---|---|---|
| Vital Images | Vitrea 4DCT Brain Perfusion option | K072821 |

## Device Description

CT Brain Perfusion for Ziostation is an add-on software feature designed to provide a color map of cerebral blood flow and pictorial illustration of perfusion-related parameters obtained on CT images of the brain. This software is designed to work within the currently cleared Ziostation image management device.

## Materials

CT Brain Perfusion for Ziostation consists entirely of software. No materials are contained in this product.

## Testing Summary

All devices met the required specifications for the completed tests.

## Summary of Substantial Equivalence

CT Brain Perfusion for Ziostation is substantially equivalent in intended use and function to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 2008

Mr. Richard Ball
Director, RA/QA
ZioSoft, Inc.
2200 Bridge Parkway, Suite 103
REDWOOD CITY CA 94065

Re: K083084
Trade/Device Name: CT Brain Perfusion for Ziostation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 14, 2008
Received: October 16, 2008

Dear Mr. Ball:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology | 240-276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 894.xxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K083084

Device Name: CT Brain Perfusion for Ziostation

Indications for Use:

Ziostation is an image processing workstation software package designed to run on standard PC hardware. It provides for the viewing, quantification, manipulation, communication, printing, and management of medical images. It is intended for use by trained medical professionals to aid in their reading and review of such data. In addition, Ziostation has the following indication:

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Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K083084

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