K080799

510(k) Summary of Safety & Efficacy

Atlas-Based Autosegmentation 510(k)

AUG - 7 2008

Submitter Name:	Computerized Medical Systems, Inc.
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Contact Person:	Kathryn Stinson – Regulatory Affairs Associate
Date Summary Prepared:	
Device Trade Name:	Atlas-Based Autosegmentation
Device Common Name:	Autosegmentation Software
Device Classification:	System, Simulation, Radiation Therapy per 21CFR892.5840
Substantial Equivalence:	BrainLAB iPlan RT Dose (K053584) Pinnacle^3 (K041577); IKOEngelo (K061006);
Level of Concern & Rationale*:	Major

*Per FDA document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," issued May 11, 2005.

4b of Table 1, "Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems…." Atlas-Based Autosegmentation (abbreviated "ABAS") does not directly control the linear accelerator that delivers the radiation. Once completed, contours are sent to a treatment planning system where dose is calculated and contours are adjusted, reviewed, approved by qualified clinicians and subject to quality assurance practices before treatment actually takes place. There is no automatic link between the ABAS software and the linear accelerator. ABAS is not a full treatment planning system and performs only an initial contouring function. However, because previous guidance has held that radiation treatment planning systems are devices of major concern, and because we believe ABAS falls under the larger category of software programs associated with treatment planning, we have assumed a "major" level of concern for the purposes of this submission.

Device Description: Contouring of radiation therapy targets and surrounding anatomical structures (also known as image segmentation) is a critical part of radiation treatment planning that can be extremely time consuming. Atlas-Based Autosegmentation (ABAS) is a software application that automates the contouring process using atlas-based autosegmentation. This method uses an already-segmented image set (atlas) to segment a set of new, user-input images using deformable registration algorithms. The contours ABAS generates are not usable for treatment as-is; they must be exported to a treatment planning system for editing. However, Atlas-based Autosegmentation provides a good starting point from which minimal editing is required, enabling the clinician to create a high quality treatment plan more efficiently.

Device Intended Use: Atlas-Based Autosegmentation is a standalone software application that produces estimates of anatomy boundary contours needed for the creation of a radiotherapy treatment plan.

Summary of Technological Characteristics Compared to Predicate Devices: ABAS is unique compared to substantially equivalent products in that it performs only autosegmentation. BrainLAB's iPlan RT Dose and Phillips/ADAC's Pinnacle[3] are fully functioning treatment planning systems that include autosegmentation, contour editing, dose calculation and plan review. IKOEngelo allows the user to edit contours in addition to providing autosegmentation capability. ABAS's sole function is to automatically generate estimated contours. The contours generated are not clinically usable as-is, and ABAS does not offer the tools necessary to edit them. The user must export the segmented image sets to a treatment planning system for contour editing, dose calculation, plan review and other necessary treatment planning activities.

ABAS uses an altas-based approach to autosegmentation, like iPlan and IKOEngelo, and allows the user to expand its library of atlases just as Pinnacle[3] allows the user to save new models and templates. Like all of the predicate devices, ABAS uses deformable registration and communicates with other treatment planning applications using DICOM.

A detailed comparison can be found in section 12 of this submittal.

Summary of Clinical Testing: Clinical trials were not performed as part of the development of this product. Clinical testing is not advantageous in demonstrating substantial equivalence or safety and effectiveness of the device since testing can be performed such that no human subjects are exposed to risk. Clinically oriented validation test cases were written and executed in-house by CMS customer support personnel. ABAS was deemed fit for clinical use.

Summary of Non-Clinical Testing: Verification tests were written and executed to ensure that the system is working as designed. Pass/fail requirements and results of this testing can be found in the ABAS Verification Test Report, which is included in section 18 of this submittal. ABAS successfully passed verification testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 7 2008

Ms. Kathryn Stinson
Regulatory Affairs Associate
Computerized Medical Systems, Inc.
1145 Corporate Lake Drive
ST. LOUIS MO 63132

Re: K080799
Trade/Device Name: Atlas-Based Autosegmentation
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN and MUJ
Dated: July 18, 2008
Received: July 20, 2008

Dear Ms. Stinson:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(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 Biometric's (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,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K080799

Statement of Indication for Use
Atlas-Based Autosegmentation 510(k)

Atlas-Based Autosegmentation is a standalone software application that produces estimates of anatomy boundary contours needed for the creation of a radiotherapy treatment plan.

Concurrence of the Center for Devices and Radiological Health,
Office of Device Evaluation (ODE)

Prescription Use ✓ OR per 21 CFR 801.109 Over the Counter Use _____

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K080799