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K&S Associates, Inc.
Diamond Edition of Setup 2000 Version 3.0
Summary of Safety and Effectiveness:

K032871 P1 of 3

Introduction

This software is designed specifically for the purpose of providing the medical physicist and other qualified health professionals a powerful and effective quality assurance tool for the analysis and verification of radiation therapy treatment plans generate by modern treatment planning computer systems. While this document describes the efforts to make this software safe and effective for it's intended use, it should be understood that the proper use of this device promotes better patient care by bridging the ever increasing gap between the sophisticated calculation capability of the modern treatment planning computers and the otherwise limited calculational resources normally available to the individuals responsible for independent verification. The use of this software also reduces operator errors through the use of active internal validation of user inputs and other machine limitations prior to performing a calculation.

Description

The Diamond Edition of Setup 2000 Version 3.0 software program is designed to operate in a Microsoft Windows environment either on a single PC or on a workstation with the treatment machine and patient data shared on a server. This software does not control any device that delivers radiation to the patient. This software does not communicate directly with the treatment machine, the primary treatment planning (RTP) computer or the record and verify system. This software does have the ability to transfer treatment data files in a standardized format (e.g. RTP Connectivity Protocol by IMPAC) from the primary treatment planning computer or R&V system to facilitate the entry of the data to the software and the transfer of data to the R&V system for electronic charting. The software calculates the treatment machine monitor units (MU or time as appropriate) or dose to validate the values calculated by the RTP computer or to provide the settings for simple treatments not requiring the RTP plan prescribed by the physician. The software provides these calculations using methods and models published in the professional literature, the specific treatment information provided by the user and the values in a treatment machine database of measured physical parameters entered and validated by the medical physicist. The results of calculations are documented in printed or electronic reports to be placed in the patient's chart.

Intended use and Substantial Equivalence

The intended use of Diamond Edition of Setup 2000 Version 3.0 is the same as the named predicated devices. The Diamond Edition of Setup 2000 Version 3.0 and the predicated devices are equivalent in the following ways:

1. Allow the calculation of MU or dose under user specified parameters.
2. Use similar calculation methods based in the literature.
3. Use a treatment machine database for look up, interpolation and calculation of results.

4. Provide a means of storing the calculations in a manner that maintains the relation to the specific patient.
5. Have reports that document the calculation parameters and results.
6. Use terminology that is commonly used in the profession.
7. Have user interfaces that allow the user to communicate with the software.
8. Have ability to transfer information from the primary treatment planning computer or record and verify systems.
9. Have the ability to perform calculations with modern treatment machine options such collimators with asymmetric jaws, dynamic wedging and multi-leaf collimators (MLC).
10. Have the ability to import treatment information files for intensity modulated radiation therapy (IMRT) having multiple segments with MLC settings and calculate the point dose at specified points of interest.
11. Have some capability to operate on a server with multiple users.
12. Have the ability to calculate and report Diode/TLD measurements.

The differences between Diamond and the predicated devices relate to the ease of use and security as follows:

1. Diamond has fewer screens and provides more information within each screen.
2. Diamond has a machine wizard to assist the medical physicist in treatment machine data entry.
3. Diamond is much faster when operating on a server with binary patient and machine files.
4. Diamond provides the features to manage the calculations of active patients (patients on treatment) and inactive patients.
5. Diamond uses a more accurate collimator scatter function through a points-eye-view of the flattening filter, the primary jaws and the MLC components to produce more accurate results.
6. Diamond provides a higher level of security of machine files with an archiving previous data files and a check-in/check-out feature to prevent multiple medical physicists on a networked system from changing data in the same machine file.
7. Diamond has the ability to store the Diode/TLD data in the patient file.
8. Diamond produces more accurate IMRT dose results through the application of more recent and more sophisticated calculation models.
9. Diamond provides a substantial Error Avoidance System (EAS) to minimize operator errors.

Technological characteristics

Diamond provides similar capabilities and functions for the basic static field treatment calculations but has many technically superior features that are based on recent advances in collimator scatter modeling and MLC simulation for IMRT.

Risk & Hazard Analysis Summary

The risk and hazard analysis provided in this submission demonstrate the traceability from the Design Controls, Software Requirements Specifications

through to the System Test Plan and the Test and Validation Logs and user documentation that every conceivable hazard to the patient and the integrity of the data files has been mitigated to the fullest extent possible. Additionally, a substantial system of internal validation checks and pre-calculation validation provide a substantial Error Avoidance System (EAS).

Summary of Safety and Effectiveness

K& S has a long history with dose calculation software beginning in 1978 with a first release to the public in 1984. This history is based on fulfilling the needs of a medical physics consulting organization by designing software to not only perform the required task but also to assist in the ongoing need to reduce errors in calculations and to help standardize the calculation methods of all members of the radiation oncology team including the medical physicist, the dosimetrist, the therapist and the radiation oncology physician. Quality patient care is achieve only when all members of the medical team participate in and are part of a coordinated quality system. The Diamond Edition of Setup 2000 Version 3.0 helps achieve this goal through a simple, reliable design that is easy to understand and easy for the operator to use. Significant effort has been expended to design, specify, code, test and produce a software product that is as safe and effective as reasonably possible under the usual conditions of cost versus benefit. This document describes this effort. After the software version has been alpha tested (System Tests and Validation Tests) at the K&S facility, a network of selected knowledgeable and qualified users, others under the supervision of K&S and QED consultants and institutions such as the MD Anderson Cancer Center test the software in a complex clinical environment to identify any needed changes. A confidential copy of their report on an earlier version of Setup 2000 is included. It is important to understand that K&S is both the customer and the developer and our professional medical physics practice depends on a reliable software product. K&S has a software quality program that includes audits of tests and records and a staff accustomed to satisfying quality issues as evidenced by three accreditations for the calibration services provided for nearly 20 years. We require this software to be accurate, reliable, dependable and efficient to serve our consulting needs and these requirements ensure that the software is thoroughly tested before release. The DOS Setup program has been in use by hundreds of highly qualified professionals across the US since 1984 without a single reported incidence of calculation error. The Windows software has been in clinical use since 2001 and has been in continuous refinement and development. It has been a slow process because we have required each incremental change to be thoroughly mastered before the next change.

In summary, we consider the Diamond Edition of Setup 2000 Version 3.0 Dose Calculation Management software to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 2004

Ms. Vivian Denton
Quality Manager
K & S Associates
1926 Elm Tree Drive
NASHVILLE TN 37210-3718

Re: K032886
Trade/Device Name: Diamond Setup 2000
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 LHN
Dated: December 17, 2003
Received: December 19, 2003

Dear Ms. Denton:

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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

K&S Associates, Inc.

Indications for Use

510(k) Number (if known): K 032886

Device Name: Diamond Edition of Setup 2000 Version 3.0

Indications For Use:

The current standard of care (AAPM, ACMP, ACR, etc.) in radiation oncology requires that the calculation results of each computer generated treatment plan be checked by some independent method. In the case of IMRT there is an additional requirement to perform measurements with ion chambers, TLD, film or other appropriate devices to ensure the accurate setup and delivery of the prescribed dose to the target organ and the limitation of dose to nearby sensitive organs. The medical physicist has the primary responsibility for these quality assurance checks and independent calculations. The intended purpose of the Diamond Edition of Setup 2000 Version 3.0 software is to provide an accurate and convenient method of independently checking, on a point dose basis, the treatment planning calculations of the primary radiation treatment-planning (RTP) computer. The primary RTP computer is capable of importing CT images of the patient, identifying target volumes, superimposing the treatment beams and optimizing the weighting and modulation of the beam to produce an acceptable radiation distribution within the patient. The Diamond Edition of Setup 2000 Version 3.0 calculates point doses under specified conditions communicated to the software through operator interaction (keyboard and mouse) or through file import.

American Association of Physicists in Medicine (AAPM)
American College of Medical Physics (ACMP)
American College of Radiology (ACR)

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032886