Best NOMOS
% Vineet Gupta, Ph.D.
Director-R&D
One Best Drive
PITTSBURGH PA 15202

October 27, 2017

Re: K170345
Trade/Device Name: SOFTDISO
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: October 5, 2017
Received: October 10, 2017

Dear Dr. Gupta:

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 (DICE) 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 (DICE) 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,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170345

Device Name

SOFTDISO

Indications for Use *(Describe)*

The SOFTDISO system is a standalone software solution designed to be used by medical physicists, radiation oncologists, and dosimetrists to have an overview of the treatment plans delivered from Treatment Systems (LINAC Systems using high energy x-rays) to the patient. This solution is to be used as a quality control check purposes only.

SOFTDISO does not provide any conclusions or policy for interpretation of the results based on the comparison results data. The output from SOFTDISO cannot be and must not be used for changing the planning or treatment strategy or as a means of proving the effectiveness of the quality control process/chain during treatment. It is the physician's responsibility to verify the working of the quality control process/chain and the correctness of the dose delivered.

Type of Use *(Select one or both, as applicable)*

[x] 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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Traditional 510(k) Summary

A. SUBMITTERS NAME

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D. DATE PREPARED

Date: 5-Oct-2017

E. ESTABLISHMENT REGISTRATION NUMBER

Corporate Office Registration Number: 2434141
Manufacturing and Packaging Registration Number: 2434141

F. DEVICE NAME

Device Trade Name: **SOFTDISO**
Common Name: Standalone Software Quality Control System
Classification Name: Medical Charged Particle Radiation Therapy System (21 CFR 892.5050)

G. DEVICE CLASS

Class II
Panel: Radiology
Product Code: IYE
Regulation Number: 21CFR 892.5050

H. STATEMENT OF INDICATIONS FOR USE

The SOFTDISO system is a standalone software solution designed to be used by medical physicists, radiation oncologists, and dosimetrists to have an overview of the treatment plans delivered from Treatment Systems (LINAC Systems using high energy x-rays) to the patient. This solution is intended to be used as a quality control check purposes only.

SOFTDISO checks the correctness of the treatment by comparing the planned dose (from a treatment planning system) with the applied dose measured from the Electronic Portal Imaging Device (EPID) during treatment delivery and presents the results. SOFTDISO does not provide any conclusions or policy for interpretation of the results based on the comparison results data. The output from SOFTDISO cannot be and must not be used for changing the planning or treatment strategy or as a means of proving the effectiveness of the quality control process/chain during treatment. It is the physician's responsibility to verify the working of the quality control process/chain and the correctness of the dose delivered.

I. DEVICE DESCRIPTION

SOFTDISO software permit an IN-VIVO dosimetric analysis (IVD) in patient for 3DCRT, IMRT and VMAT beams using a Si-EPID portal systems.

The dosimetric analysis consists of two tests elaboration, dose reconstruction in the isocenter point and EPID images γ-analysis. In case of out of tolerance levels, the system is capable of underline the right type of quality control useful to remove the causes of discrepancy.

SOFTDISO software is based on the usage of generalized correlation factors between transit signals measured by EPID and doses measured in water equivalent solid phantom, along the beam central axis.

SOFTDISO software uses generalized functions taken from measurements of 70 beams of Varian, Elekta and Siemens linacs. So only a small set of dosimetric measurements must be performed by the user for the software commissioning, and some of those measurements are already performed during the linac's beams calibration. In particular some of the measurements that the user performs include calculating the beam dose in cGy/UM in reference conditions (field 10.10 cm2 at drif =10 cm depth), the beam quality indicator (TPR20, 10) and the attenuation factor WF for wedged beams. The user also performs a measure of the EPID signal in reference condition (field 10.10 cm^2 at SED distance) for EPID calibration.

SOFTDISO software can use information coming from record and verify systems through DICOM and DICOM-RT protocols. DICOM protocol is used for transferring images from CT and from EPID and the DICOM-RT protocol is used for transferring information related to the TPS system.

As soon as the treatment plan and the EPID images (fraction images for each day) are imported into the system, the user is able to visualize the comparison results.

At the end of fraction SOFTDISO provides result for two tests:

- Calculation of R ratio between in patient reconstructed dose and the one planned by the TPS
- Gamma analysis between a reference EPID image and a current one with $P_{\gamma<1}$ e γ_{mean} indexes

SOFTDISO can print the tests results and once signed by a Medical Physicist it can become part of the patient's clinical folder. The patient images and the comparison results are stored in the system's internal database for easy access at any time.

J. PREDICATE DEVICE INFORMATION

The predicate devices identified within this submission are as follows:

a. Math Resolution, LL, Dosimetry Check with Exit Dose (510(K) No. K101503 (Decision Date: 04-August-2010)).

K. COMPARISON TO THE PREDICATE DEVICE

This section provides the summary of comparison of SOFTDISO to the predicate device.

Table 1 Indications for Use & Intended Use Comparison

	Proposed Device **SOFTDISO**	**Predicate Device** **Dosimetry Check with Exit Dose (K101503)**
Indications for Use	The SOFTDISO system is a standalone software solution designed to be used by medical physicists, radiation oncologists, and dosimetrists to have an overview of the treatment plans delivered from Treatment Systems (LINAC Systems using high energy x-rays) to the patient. This solution is to be used as a quality control check purposes only. SOFTDISO does not provide any conclusions or policy for interpretation of the results based on the comparison results data. The output from SOFTDISO cannot be	The product is to be used by radiation oncologist, dosimetrist, and radiation therapy physicist to check the correctness of the x-ray treatment fields from high energy treatment machines that are planned to be or have been applied to a patient. This product is to be used in addition to the treatment planning system to provide a means for additional and redundant verification that the plan is in fact successfully accomplished. This product is not a treatment planning system and is not to be used as one. This product only checks the applied dose based on the

	and must not be used for changing the planning or treatment strategy or as a means of proving the effectiveness of the quality control process/chain during treatment. It is the physician's responsibility to verify the working of the quality control process/chain and the correctness of the dose delivered.	measurement of each x-ray field and a theoretical calculation. This product does not provide any quality assurance that the fields are. in fact correctly applied to and correctly aligned with the patient anatomy as planned. In addition, the product may be used to display the above dose on other fused image sets which could provide additional clinical information to the radiation oncologist regarding the treatment.

Table 2 General Comparison

Comparison Item	**Proposed Device SOFTDISO**	**Predicate Device Dosimetry Check with Exit Dose (K101503)**
Classification Name	Quality Control For Medical Charged Particle Radiation Therapy System	Quality Control For Medical Charged Particle Radiation Therapy System
Product Code	IYE	IYE
Class	II	II
Regulation Number	892.5050	892.5050

The indications for use for both the proposed device (SOFTDISO) and the Predicate Device (Dosimetry Check with Exit Dose) are similar. Both the devices are intended to be used as QA check to determine the correctness of the dose delivery by using the planned dose and delivered dose as input to the software to generate the report of differences. Both the devices use the planning images and exit images, and are designed to work only on photons (x-rays). Since the target population, indications for use, intended use, and the technical features of the proposed device (SOFTDISO) are similar to that of the predicate device, any minor difference in features do not raise any concerns for safety, performance, or effectiveness of the device; thus indicating that the proposed device is substantially equivalent to its predicate device. The characteristics/features of SOFTDISO with respect to the predicate device is described in detail the comparison chart in the submission. The similarities and differences are discussed in detail as part of this submission.

L. SUMMARY OF TESTING

Design verification and validation testing was performed to ensure that the device functionality works as per its intended use, all risks are mitigated, and the product conforms to the required standards. The details of the design verification and validation activities are explained in the submission.

Non-Clinical Testing:

Non-clinical testing included functional testing, performance testing, verification of risk control measures implemented in the software, and installation testing.

Validation:

External validation to validate the accuracy of dosimetry procedure for 3DCRT was performed at three different clinical sites. The results of R ratios for all 192 tests performed were within the acceptable tolerance of ± 5%. The γ% and γ_{mean} indexes for all tests were ≥ 95% and ≤ 0.3 respectively.

To validate the accuracy of dosimetry procedure for IMRT and VMAT, external validation was performed at three and two different clinical sites respectively. The results of the R ratios for 48 tests for IMRT was well within the acceptable tolerance of ± 5%. The results of the R ratios for 60 tests for VMAT were well within the acceptable tolerance of ± 5%. The γ% and γ_{mean} indexes for all tests for IMRT and VMAT were ≥ 95% and ≤ 0.3 respectively.

Clinical validation was performed by applying in-vivo dosimetry checks on 1287 treatments. The results of the in-vivo dosimetry check indicated that SOFTDISO was easy to setup and use. The average analysis time was about 2.5 mins per patient (2 hours for an average of 50 patients/day).

Clinical validation was performed on 823 patient data who underwent 3DCRT (340) and VMAT (483) treatments. The results of the study indicated that the SOFTDISO system was able to identify errors that occur during treatment that were a result of inadequate quality controls (for example: patient setup, laser misalignment, TPS beam-implementation) and patient morphological changes (for example: tumor shrinkage, gas pockets, loss of patient weight).

Conclusion:

Detailed results of these tests are included as part of this submission. The verification and validation results demonstrate that the SOFTDISO system met its design requirements and specifications, is safe and effective to use for its intended purpose, and conforms to the applicable sections of standards that includes IEC 63204:2006: Medical device software – Software life cycle processes, BS EN 62366:2008: Medical devices -Application of usability engineering to medical devices.