April 26, 2020

ControlRad, Inc
% Linda Braddon
CEO
Secure BioMed Evaluations
7828 Hickory Flat Highway Suite 120
Woodstock, Georgia 30188

Re: K200238
Trade/Device Name: ControlRad Sterile Cover
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape And Drape Accessories
Regulatory Class: Class II
Product Code: KKX
Dated: January 30, 2020
Received: January 31, 2020

Dear Linda Braddon:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

CAPT Elizabeth F. Claverie M.S.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020

See *PRA Statement on last page.*

510(k) Number *(if known)*

K200238

Device Name

ControlRad Sterile Cover

Indications for Use *(Describe)*

ControlRad Sterile Cover is a single use sterile equipment cover intended for use by professionals in a sterile clinical setting to cover the ControlRad Trace Tablet and create a sterile barrier between the tablet and the rest of the sterile field to prevent contamination during various procedures.

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

☐ Prescription Use (Part 21 CFR 801 Subpart D) X Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

K200238: ControlRad, Inc
275 Scientific Drive NW#1100
Norcross, GA 30092

510(k) Summary K200238

In accordance with 21 CFR 807.87 (h) and 21 CRF 807.92, the 510(k) summary for ControlRad Sterile Cover is provided below.

Date	April 21, 2020
Submitted by	ControlRad, Inc 275 Scientific Drive NW #1100 Norcross, GA 30092 Phone: (800)-522-5148
510(k) Contact	Secure BioMed Evaluations Linda Braddon, Ph.D. 7828 Hickory Flat Highway Suite 120 Woodstock, GA 30188 770-837-2681 Regulatory@SecureBME.com
Trade Name	ControlRad Sterile Cover
Common Name	Sterile Cover
Code –Classification	KKX: Class II
Predicate	K101350, RadScan Equipment Slicker
Reference Device	K141438, Whitney Medical Solutions eShield

Device Description

The ControlRad Sterile Cover is a terminally sterilized device intended to cover the ControlRad tablet in order to operate a ControlRad tablet in a sterile environment.

Indications for Use

ControlRad Sterile Cover is a single use sterile equipment cover intended for use by professionals in a sterile clinical setting to cover a ControlRad Tablet and create a sterile barrier between the tablet and the rest of the sterile field to prevent contamination during various procedures.

Technological Characteristics

The subject device has similar technological characteristics as the predicates in terms of principles of operation, intended use, material, performance, and biocompatibility.

Technological Characteristics Comparison Table

The ControlRad Sterile Cover is similar in function and intended use to the predicate and/or reference device. A comparison of the subject device to the predicate devices is shown in the following table.

Trait	ControlRad Sterile Cover	RadScan Equipment Slicker (Predicate Device)	Whitney Medical Solutions eShield (Reference Device)	Comparison
510(k) number	K200238	K101350	K141438	N/A
FDA Regulation	878.4370	878.4370	878.4370	Same
Product Code	KKX	KKX	KKX	Same
Product Classification	Class II	Class II	Class II	Same

Trait	ControlRad Sterile Cover	RadScan Equipment Slicker (Predicate Device)	Whitney Medical Solutions eShield (Reference Device)	Comparison
Use	Prescription Use Part 21 CFR 801 Subpart D	Over-the-Counter Use Part 21 CFR 801 Subpart C	Over-the-Counter Use Part 21 CFR 801 Subpart C	Same
Mechanism of Action	Create a plastic sterile barrier around medical equipment	Create a plastic sterile barrier around medical equipment	Create a plastic sterile barrier around electronic equipment	Same
Composition	Polyethylene draping on ABS frame	Not Disclosed	Polyethylene	Same
Single Use	Yes	Yes	Yes	Same
Physical Specifications	1100mm x 1200mm (43.3in x 47.2in)	Multiple Sizes	Width: 9 – 14 inches Height: 14 – 22 inches All Models	Different
Patient Contacting	No	No	No	Same
Packaging	PET blister pack with TYVEK lid	Not Disclosed	Single barrier Tyvek/-LDPE film	Same
Sterilization	EO	Sterile (Not Disclosed)	Gamma	Different

Biocompatibility

The subject device is categorized as a non-patient contacting device and the device was found. Cytotoxicity testing was performed to evaluate the safety of the device.

Non-clinical Testing

The subject device has equivalent performance characteristics in regard to liquid barrier and blood-born pathogen penetration as assessed by ASTM F1671. Additional characterization of mechanical performance including tensile strength and tear resistance via ASTM D882 and ASTM D1004, respectively, was performed.

Summary of Non-clinical Testing

Name of Test Method	Purpose	Acceptance Criteria	Results
Liquid Barrier	Ensure cover protects against liquid penetration	No liquid penetration	PASS
Viral Penetration via ASTM F1671 / F1671M-13	Ensure cover protects against viral penetration	No viral penetration	PASS
Tensile Strength via ASTM D882	Characterization of tensile strength	Characterization testing	PASS
Tear Resistance via ASTM D1004	Characterization of tear resistance	Characterization testing	PASS
ISO 11135-1:2104: Sterilization of Health-Care Products – Ethylene Oxide	Ensure sterility assurance level of 10^{-6}	SAL 10^{-6}	PASS
ASTM F88/F88M-15	Seal Strength (TyVek pouch - primary sterile barrier)	Seal Strength > 1lbf for all seals	PASS
ASTM F1929-15	Dye Penetration	No dye penetration via visual inspection	PASS
ISO 10993-5 Biological evaluation of medical devices: Part 5 Tests for in vitro Cytotoxicity	Biocompatibility Testing	Cell culture treated with test sample exhibited no reactivity (Grade 0)	PASS Non-cytotoxic

Conclusions

The conclusions drawn from the nonclinical tests demonstrate that the ControlRad sterile cover is as safe, as effective, and performs as well as or better than the legally marketed device RadScan Equipment Slicker (K101350).