September 20, 2019

CivaTech Oncology, Inc.
% Blix Winston, MPA, MS
Director Regulatory Affairs
TAMM Net, Inc.
2600 Mullinix Mill Road
MT. AIRY MD 21771

Re: K191324
Trade/Device Name: CivaDerm™
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: Class II
Product Code: ONL, KXK
Dated: September 4, 2019
Received: September 4, 2019

Dear Mr. Winston:

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,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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 below.

510(k) Number *(if known)*
K191324

Device Name
CivaDerm™

Indications for Use *(Describe)*
CivaDermPd103 indicated for treatment of temporary intraoperative or surface application to treat selected localized tumors. It can be used either as primary treatment or as treatment for residual disease after excision of primary or recurrent tumors.
This brachytherapy source may be used concurrently with or following treatment with other interventions, such as external beam therapy.

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

☒ 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

1. 510(k) Submitter:

K191324

Mrs. Suzanne Babcock
CivaTech Oncology, Inc.
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Email: sbabcock@civatechoncology.com

2. Submission Correspondent:

Blix Winston, MPA, MS
TAMM Net, Inc., Director Regulatory Affairs
2600 Mullinix Mill Road
Mt. Airy, MD 21771

Ph: 301-607-9185
Email: blix@tammnet.com

3. Date Prepared: May 14, 2019

4.

Name of Device:	CivaDerm™
Common Name:	Radionuclide Brachytherapy Source
Classification Name:	Radionuclide Brachytherapy Source 21 CFR 892.5730, Product Code ONL, KXK
Classification:	Class II
Product Code:	ONL, KXK
510k number:	K191324

5. Identification of devices to which the submitted claims equivalence:

Device Name: RIC Conformal Source Model 100 Brachytherapy Source
510K Number: K090321
Classification: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: ONL, KXK
Concurrence Date: 05/27/2009

6. Device Description:

The CivaDerm utilizes biocompatible materials and bioabsorbable polymers to encapsulate Pd-103, a radionuclide with a long history in radiotherapy. CivaDerm is a

planar unidirectional source intended to deliver x-ray radiation for surface brachytherapy procedures.

By utilizing gold backing with the radionuclide, CivaDerm provides radiation in one direction. This allows it to target radiation dose to a contoured exterior surface without irradiating surrounding healthy tissue.

7. Indications for Use

CivaDerm^{Pd103} indicated for treatment of temporary intraoperative or surface application to treat selected localized tumors. It can be used either as primary treatment or as treatment for residual disease after excision of primary or recurrent tumors.
This brachytherapy source may be used concurrently with or following treatment with other interventions, such as external beam therapy.

8. Characteristics of the device in comparison to those of the predicate device(s)

The function of the CivaDerm for temporary surface applications is the same as the predicate device. CivaDerm^{Pd103} indicated for treatment of temporary intraoperative or surface application to treat selected localized tumors. It can be used either as primary treatment or as treatment for residual disease after excision of primary or recurrent tumors.
This brachytherapy source may be used concurrently with or following treatment with other interventions, such as external beam therapy.

9. Safety and Performance:

All required non-clinical testing has been successfully performed according to published industry standards. CivaDerm finished devices are tested and meet acceptance criteria determined by product design specifications to verify each device is safe and effective. Products released from manufacturing meet requirements for product integrity, apparent activity, external contamination, among others. The device, as designed, is as safe and will be as effective as its predicate device.

10. Conclusion

Based on the design, material, function and intended use discussed herein, CivaTech Oncology®, Inc. believes the CivaDerm is substantially equivalent to predicate devices currently marketed under the Federal Food, Drug and Cosmetic Act.