



December 5, 2025

OncoPatch, Inc.
% Sam Murray
Regulatory Consultant
TAMM Net, Inc.
3101 Cobb Pkwy
Atlanta, Georgia 30339

Re: K252296
Trade/Device Name: OncoPatch
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: Class II
Product Code: KXX
Dated: July 22, 2025
Received: July 23, 2025

Dear Sam Murray:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Digitally signed by Michael D.

O'hara -S

Date: 2025.12.05 14:49:04 -05'00' For

Lora Weidner

Assistant Director

DHT8C: Division of Radiological

Imaging and Radiation Therapy Devices

OHT8: Office of Radiological Health

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K252296

Device Name

OncoPatch

Indications for Use (Describe)

OncoPatch is indicated for the surface treatment of localized tumors. It is designed to deliver radiation therapy for the treatment of superficial lesions. It can be used either as primary treatment or as treatment for residual disease after excision of primary or recurrent tumors.

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.

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1. 510(K) SUMMARY

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR § 807.92.

1.1. Submitter's Information

Name: OncoPatch, Inc.
Address: 12635 East Montevue Blvd., Suite 100
Aurora, CO 80045
Phone: (720) 778-1317
Contact Person: David Westerly
Co-Founder & CEO
Preparation Date: 5 December 2025

1.2. Device Name

Trade Name: OncoPatch
Common Name: Radionuclide Brachytherapy Source
Classification Name: Radionuclide Brachytherapy Source
Regulation 21 CFR § 892.5730
Regulatory Class: Class II
Product Code KXX

1.3. Legally Marketed Predicate Device

The legally marked predicate is the RIC Conformal Source Model 100 Brachytherapy Source (RIC-100) (K090321).

1.4. Device Description

The OncoPatch device is engineered for the surface treatment of skin cancers, such as basal and squamous cell carcinoma, as well as for other skin conditions, including keloids. Using yttrium-90 (Y-90) as the radioactive source, this device delivers low-energy beta radiation directly to the skin surface, targeting cancerous or abnormal tissue while sparing underlying healthy tissue. The OncoPatch device makes use of radioactive patches constructed from thin, polymer-coated foils containing Y-90. These foils are adhered to the underside of a plastic or metal composite shield, which ensures safety for both the patient and healthcare providers during treatment. The patch and shield are coupled with an applicator. The applicator uses collimators with predetermined shapes and sizes that assume a flat patient geometry. The OncoPatch is secured temporarily to the patient surface for single or multiple treatment fractions, typically with short (< 60 min) treatment durations.

1.4.1. Brief Written Description of the Device

The OncoPatch device is a surface brachytherapy system that applies the principles of low-energy beta radiation to treat localized skin lesions. Its therapeutic function is based on the physical properties of yttrium-90 (Y-90), a pure beta emitter with short penetration range and high surface dose deposition. This enables concentrated radiation delivery to the epidermis and upper dermis, while minimizing exposure to deeper tissues.

The core technology centers on a foil-based Y-90 source created by neutron activation of yttrium-89. These thin metal foils are polymer-coated to contain the radioactive material and minimize contamination risk. The foil source is mechanically supported by a rigid shield that not only ensures positional stability but also serves to absorb backward-directed radiation. Magnetic coupling elements integrated into the shield facilitate precise alignment with the treatment applicator.

The applicator includes Y-90 patch and shield assembly which is coupled with a skin collimator to deliver the treatment. These components are available in fixed geometries and are fabricated from rigid polymers or composites and metal compatible with medical use.

The system is designed for single-fraction or fractionated therapy, allowing flexibility in clinical implementation while ensuring consistent and directional surface radiation.

1.5. Intended Use

OncoPatch is intended for the treatment of cancer and other lesions by temporary surface irradiation.

1.6. Indications for Use

OncoPatch is indicated for the surface treatment of localized tumors. It is designed to deliver radiation therapy for the treatment of superficial lesions. It can be used either as primary treatment or as treatment for residual disease after excision of primary or recurrent tumors.

1.7. Substantial Equivalence Discussion

The OncoPatch is substantially equivalent to the legally marketed predicate device RIC-100 (K090321) with respect to intended use, mechanism of action, technological characteristics, performance, and safety. A comparison of the similarities and differences of the OncoPatch and cleared predicate are provided in Table 1.

Table 1: Predicate Comparison

Specification/ Characteristic	Subject Device	Predicate Device	Comparison
	OncoPatch	RIC Conformal Source Model 100 Brachytherapy Source (K090321)	
Classification	21 CFR § 892.5730, Class II	21 CFR 872.5570, Class II	Identical
Product Code	KXK	KXK, ONL	Substantially Equivalent
Intended Use	Treatment of cancer by temporary surface irradiation.	Treatment of cancer by surface irradiation.	Identical
Indications for Use	OncoPatch is indicated for the surface treatment of localized tumors. It is designed to deliver radiation therapy for the treatment of superficial lesions. It can be used either as primary treatment or as treatment for residual disease after excision of primary or recurrent tumors.	RIC Conformal Source Model 100 Brachytherapy Source, containing Phosphorus-32 with activity up to 200 mCi is indicated for treatment of temporary intraoperative, interstitial, intracavitary 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. Chordomas, chondrosarcomas, soft tissue sarcomas, skin cancers and other accessible tumors could be commonly treated by the RIC Conformal Source Model 100 Brachytherapy Source, containing Phosphorus-32.	Substantially Equivalent
Mode of Use	Rx Only	Rx Only	Identical
Radionuclide	Yttrium-90 (Y-90)	Phosphorus-32 (P-32)	Substantially Equivalent
Radionuclide Half life	64.1 hours	14.3 Days	Substantially Equivalent
Type of Radiation	Beta particles	Beta particles	Identical
Source Configuration	Foil array	Planar array	Substantially Equivalent
Radioactivity	200 mCi	200 mCi	Identical

Specification/ Characteristic	Subject Device	Predicate Device	Comparison
	OncoPatch	RIC Conformal Source Model 100 Brachytherapy Source (K090321)	
End Point Energy	2.28 MeV	1.71 MeV	Substantially Equivalent
Non-radioactive Materials	Composite tungsten (collimator), Photopolymer (adapter/shield), Neodymium (magnets)	Polymeric Film, silicone	Substantially Equivalent
Provided Sterile	No	No	Identical

1.7.1. Statement on Substantial Equivalence

The proposed device and predicate device are both surface brachytherapy systems intended to deliver localized radiation for the treatment of superficial tumors. Both devices operate on the same principle of beta-emitting radionuclide therapy and are designed for temporary, non-invasive application to the skin. The proposed and predicate devices share core technological characteristics including intended use, energy source (beta radiation), manual operation, and customizable treatment geometry. Differences in radionuclide (Yttrium-90 vs. Phosphorus-32), source configuration, and shielding materials have been thoroughly evaluated through bench testing and dosimetric analysis. These differences do not alter the intended therapeutic function and do not raise new questions of safety or effectiveness.

1.8. Performance Data

Performance requirements were established through a comprehensive risk management process in accordance with ISO 14971:2019. Non-clinical bench testing included shielding and bremsstrahlung attenuation, relative and absolute dose distribution accuracy, simulated-use, end-to-end testing of fit, stability, and dose delivery on an anatomically relevant phantom, simulated distribution and package integrity testing, and material characterization / biocompatibility evaluation of the patient-contacting components.

Key acceptance criteria required that surface registration errors remain within clinically acceptable ranges for accurate targeting, that dose and depth-dose profiles remain within predefined dosimetric agreement limits, and that patch activity assays remain within an acceptable tolerance around the nominal activity. Criteria also required that ambient dose rates remain within institutional and regulatory radiation safety limits for handling and transport, that device form and function are preserved following a simulated distribution cycle per ASTM D7386-16, and that material characterization per ISO 10993-18 identifies no new or unexpected chemical constituents of concern. All tests met their respective acceptance criteria and confirmed that the OncoPatch device performs as intended and is suitable for its proposed use.

Collectively, these non-clinical data demonstrate that the OncoPatch device delivers dose, provides shielding, maintains mechanical stability, and withstands shipping stresses in a manner that is comparable to the legally marketed predicate device, and that the materials are suitably biocompatible for their intended use. Therefore, the OncoPatch device is as safe and effective as, and performs as well as the predicate device.

1.8.1. Clinical Studies

Clinical testing was not necessary for the demonstration of substantial equivalence.

1.9. Conclusions

The OncoPatch device employs the same technological principles, intended use, and core therapeutic mechanism as the identified predicate device. Differences in radionuclide selection, source configuration, and shielding design have been evaluated through comprehensive non-clinical testing. These differences do not raise new questions of safety or effectiveness and do not alter the clinical application of the device. Therefore, the OncoPatch is substantially equivalent to the predicate device.