October 16, 2024

Varian Medical Systems, Inc.
Lynn Allman
Senior Director, Regulatory Affairs
3100 Hansen Way
Palo Alto, California 94304

Re: K242794
Trade/Device Name: ONCOZENE Microspheres
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular embolization device
Regulatory Class: Class II
Product Code: KRD
Dated: September 16, 2024
Received: September 16, 2024

Dear Lynn Allman:

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,

Finn E. Donaldson -S

Digitally signed by Finn E. Donaldson -S
Date: 2024.10.16 14:05:33 -04'00'

Finn Donaldson
Assistant Director (Acting)
DHT2C: Division of Coronary and
Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K242794

Device Name
ONCOZENE Microspheres

Indications for Use *(Describe)*
ONCOZENE Microspheres are intended for embolization of arteriovenous malformations and hypervascular tumors including hepatoma.

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.**

# PREMARKET NOTIFICATION

510(k) Summary

ONCOZENE Microspheres

The following information is provided as required by 21 CFR 807.92

## I. Submitter's Information:


| | |
|---|---|
| Name and Address: | Varian Medical Systems Inc. |
| | 3100 Hansen Way |
| | Palo Alto, CA 94304-1038 |
| Manufacturer: | Varian Medical Systems, Inc. |
| | 9825 Spectrum Drive, Building 2 Austin, TX 78717 |
| Contact Name: | Lynn Allman, Senior Director Regulatory Affairs |
| E-mail: | submissions.support@varian.com |
| Date Prepared: | October 15, 2024 |


## II. Device Information:

| | |
|---|---|
| Proprietary Name: | ONCOZENE Microspheres |
| Common/ Usual Name: | Microspheres for embolization |
| Classification Name: | Device, Vascular, for Promoting Embolization |
| Classification Panel: | Cardiovascular |
| Regulation Number: | 21 CFR Part 870.3300 |
| Product Codes: | KRD |

## III. Predicate Device:

ONCOZENE Microspheres (K141209)

## IV. Subject Device Description:

ONCOZENE Microspheres (hereafter may be referenced as ONCOZENE Microspheres or ONCOZENE) are spherical, tightly calibrated, biocompatible, non-resorbable, hydrogel microspheres coated with an inorganic perfluorinated polymer shell (Polyzene-F). The microspheres are suspended in liquid and then injected into the bloodstream to permanently occlude blood vessels. They are used to stop bleeding when the underlying lesion is not likely to heal or block arteries supplying a tumor to cause tumor necrosis and/or shrinkage.

ONCOZENE Microspheres are sterile, single use devices and are supplied in pre-filled 20 ml syringes containing 2ml or 3 ml of microspheres in approximately 7 ml of transport solution. The ONCOZENE Microspheres are available in 40, 75 and 100 µm sizes.

## V. Intended Use/ Indications of Use Statement:

**ONCOZENE Microspheres**

ONCOZENE Microspheres are intended for embolization of arteriovenous malformations and hypervascular tumors including hepatoma.

## VI. Substantial Equivalence Discussion:

ONCOZENE Microspheres are substantially equivalent to the legally marketed ONCOZENE Microspheres, cleared by FDA (K141209). Both devices have the same indications for use and the same technological characteristics. Both devices are spherical, non-resorbable polymer microspheres which are delivered through a microcatheter to embolize a target vessel. While there are no technological differences, the subject device incorporates an updated syringe due to end of life of the previously used syringe. The potential impacts of this change, including mechanical performance, biocompatibility, sterility, packaging and shelf-life, have been evaluated and demonstrated that the subject device meets all device specifications of the predicate device.

## VII. Performance Data:

The following performance data were provided in support of the substantial equivalence determination.

### 1. Non-clinical Testing:

ONCOZENE Microspheres underwent non-clinical testing to demonstrate the design and performance met the established design criteria and is substantial equivalent to the predicate device. The subject device successfully completed mechanical testing to ensure the device with the new syringe met all related specifications. Mechanical testing was performed to verify the Syringe Volume Identification.

### 2. Sterilization:

ONCOZENE Microspheres are moist heat (steam) sterilized to ensure a minimum sterility assurance level of $10^{-6}$ in accordance with ISO 17665-1, ISO 11138-1, ISO 11737-1 and ISO 11737-2. A new sterilization validation was performed to support this submission. ONCOZENE Microspheres are sterilized using the overkill approach, and half cycles were used to validate the process. Full cycle testing for heat penetration and half cycle testing for process challenge devices were performed, and results met all acceptance criteria.

### 3. Biocompatibility:

Biocompatibility testing of ONCOZENE Microspheres in accordance with ISO 10993-1 demonstrated that the patient-contacting components are biocompatible. Testing was performed to demonstrate compliance to:

- ISO 10993-3 Genotoxicity
- ISO 10993-4 Hemocompatibility
- ISO 10993-5 Cytotoxicity
- ISO 10993-6 Implantation Effects
- ISO 10993-10 Irritation and Sensitization
- ISO 10993-11 Material Medicated Pyrogenicity
- ISO 10993-11 Subacute/Subchronic Systemic Toxicity
- ISO 10993-17 Toxicological Risk Assessment of Chemistry Results
- ISO 10993-18 Chemical Characterization of Materials

- ISO 10993-23 Irritation

**4. Packaging Integrity and Shelf Life:**

Packaging integrity and shelf-life testing for ONCOZENE Microspheres was performed in accordance with ISO 11607-1 and ISO 11607-2 and supports a three-year shelf-life. Testing performed:

- Label adhesion
- Label legibility
- Packaging seal integrity
- Bubble leak test
- Peel strength test
- Dye penetration

## VIII. Conclusion:

As described above, the subject device and the predicate device have the same intended use and the same technological characteristics. To evaluate the impact of the updated syringe, performance testing was conducted as described. The results of the testing demonstrate that the subject device, ONCOZENE, is substantially equivalent to the predicate device.