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**510(k) Summary**

1. Sponsor Name — ONC Solutions, Inc.
   Address — 84 Sugar Hill Lane, Manchester, NH 03109
   Contact Phone — (603) 566-5001
   Contact Fax — (603) 206-5131

   Contact Individual — John Schwamb
   Prepared On — June 13, 2007

2. Device Name

   Proprietary Name: ONC Marker
   Common/Usual Name: ONC Marker
   Classification Name: Accelerator, Linear, Medical

3. Identification of Predicate or Legally Marketed Device

   The predicate devices for the ONC Marker are:
   K031206 RadioMed Soft Tissue Marker
   K070305 Preloaded RadioMed Soft Tissue Marker
   17G, 18G, 19G Introducer Needles manufactured by CP Medical (Class I – exempt)

4. Device Description

   ONC Markers exist as a series of individual gold ring members connected over a gold inner wire. The ring members can be of different diameters and different quantities can be joined together to form longer length markers. The markers will range in nominal diameter from 0.35mm to 1.2mm. The markers will range in overall length from 10mm to 60mm.

   ONC Markers are packaged in two different formats:
   A. Markers inside sterile packages for single use only
   B. Markers inside Preplugged Introducer Needles, inside sterile packages for single use only

   Sterilization is achieved by a validated EO sterilization method.

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ONC Markers will be manufactured, labeled, and packaged in accordance with the current FDA QSR. To ensure compliance to specifications, upon completion of the manufacturing process the device will be inspected and tested in accordance with ONC Solutions' standard operating procedures.

ONC Markers are typically delivered through one of the preloaded introducer needles supplied by ONC Solutions. ONC Markers may also be loaded into similar needles at the implantation site.

5. Intended Use

The intended use for this new device is identical to that of its two predicate devices.

The ONC Marker is indicated for use to radiographically mark soft tissue for future therapeutic procedures.

6. Comparison of Technological Characteristics

The fundamental scientific technology of the modified device has not changed.

Predicate Devices:
K031206 RadioMed Soft Tissue Marker
K070305 Preloaded RadioMed Soft Tissue Marker

- The material used for both of the predicate devices and the ONC Marker is pure metallic gold.
- The diameter range for both of the predicate devices and the ONC Marker are 0.35mm to 1.2mm.
- The overall length range for both of the predicate devices and the ONC Marker is 10mm to 60mm.
- The intended use for both of the predicate devices and the ONC Marker is identical.

The change to this product includes the following:

- Predicate devices exist in the form of a coil while the modified device is in the form of multiple ring members joined over an inner wire.

7. Performance Testing

Summary of Standards Achieved:
FDA QSR 21 CFR Part 820 Current Good Manufacturing Practices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL 18 2007

Mr. John Schwamb
President
ONC Solutions, Inc.
84 Sugar Hill Lane
MANCHESTER NH 03109

Re: K071673
Trade/Device Name: ONC Marker
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: June 13, 2007
Received: June 19, 2007

Dear Mr. Schwamb:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology | 240-276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 894.xxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known):

Device Name: ONC Marker K071673

Indications for Use: ONC Marker is indicated for use to radiographically mark soft tissue for future therapeutic procedures.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K071673