K023220

OCT 25 2002

VARIAN
medical systems

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**Premarket Notification [510(k)] Summary**
**as required by 21 CFR 807.92**

**Date summary was prepared:**

September 18, 2002

**Submitter's Name:**

Varian Medical Systems
3100 Hansen Way
Palo Alto, CA 94304

**Contact Person:**

Linda S. Nash
Corporate Director, Regulatory Affairs and Quality Assurance
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**Device Name:**

VariSource Breast Template System

**Classification Name:**

System, Applicator, Radionuclide, Remote-Controlled

**Predicate Device:**

Applicators for Varian VariSource Remote High Dose Rate Afterloader – Interstital Needle Applicator

**Intended Use:**

The VariSource Breast Template System is indicated for high-dose rate Brachytherapy irradiation of the breast or chest wall. The system offers a means of performing interstitial implants with a fixed geometry, for the treatment of breast carcinoma. A pair of a series of Templates are fixed in place relative to one another with the Breast Bridge. The Breast Bridge is also used to hold the

Templates over the breast during needle insertion and can be adjusted, via a ratchet mechanism to achieve the required template spacing.

**Technological Characteristics:**

See the attached "Specification Comparison Chart", Tab G

## SDD FEATURE COMPARISON

| Feature | Varian Part Description & Number. | Predicate Device |
|---|---|---|
| | **Breast Bridge and Template System Pt # AL13011000** | **Applicators for Varian VariSource Remote High Dose Rate Afterloader** |
| 1. Intended use | *HDR Brachytherapy* | *HDR Brachytherapy* |
| 2. Indications for use | *See above* | *See above* |
| 3. Target population | *N/A* | *N/A* |
| 4. Design | *The Breast Bridge and Template System is designed to make implanting needles, particularly through the breast, in a fixed geometric pattern easily achievable. The design places templates with holes in a triangular pattern (Paris geometry) on either side of the breast. A ratchet mechanism holds these templates in place while needles are implanted through the Breast. The Needles are NOT part of this product. This product is simply a tool to make it easy to insert needles in a fixed pattern.* | *Interstitial Needle Applicators* |
| 5. Materials | *Stainless Steel ratchet, polycarbonate (USP class VI approved) templates* | *Stainless Steel* |
| 6. Performance | *N/A* | *N/A* |
| 7. Sterility | *Autoclave* | *Autoclave* |
| 8. Biocompatibilty | *Fully biocompatible Stainless Steel and Polycarbonate used.* | *Fully biocompatible Stainless Steel used.* |
| 9. Mechanical safety | *N/A* | *N/A* |
| 10. Chemical safety | *N/A* | *N/A* |
| 11. Anatomical sites | *Breast, Chest Wall* | *Breast, Chest Wall and others including Prostate.* |
| 12. Human factors | *Controlled through VariSource Afterloader.* | *Controlled through VariSource Afterloader.* |
| 13. Energy used and/or delivered | *N/A* | *N/A* |
| 14. Compatibility with the environment and other devices | *Uses 18 gauge needles* | *Includes 18 gauge needles* |
| 15. Where used | *BrachyTherapy treatment unit* | *BrachyTherapy treatment unit* |
| 16. Standards met | *No applicable device standard* | *No applicable device standard* |
| 17. Electrical safety | *N/A* | *N/A* |
| 18. Thermal safety | *N/A* | *N/A* |
| 19. Radiation safety | *N/A* | *N/A* |
| 20. Predicate Device Clearance number | *N/A* | *K952913* |

| Feature | Varian Part Description & Number. | Predicate Device |
|---|---|---|
| | **Breast Bridge and Template System Pt # AL13011000** | **Applicators for Varian VariSource Remote High Dose Rate Afterloader – Interstitial Needle Applicator** |
| Needle material | *Template is constructed from a stainless steel ratchet and polycarbonate templates* | *Stainless steel shaft, Aluminium coupling, Nylon suture button.* |
| Needle dimensions | *Template facilitates the use of 18 ga., needles* | *18-21 ga., 10 – 20 cm Dia. 0.8 – 1.3 mm* |
| Needle obturator | *No* | *Yes* |
| Needle obturator material | *N/A* | *Tungsten* |
| Needle cap material | *N/A* | *Aluminium* |
| Obturator cap material | *N/A* | *Aluminium* |
| Packaged individually with obturator | *N/A* | *Yes* |
| Sterility | *Not supplied sterile* | *Sterile via gamma radiation* |
| Sterility assurance level | *N/A* | $10^{-6}$ |
| Sterilisation cycle validation | *N/A* | *AAMI guideline for Gamma radiation sterilisation (AAMI ST32 October, 1991)* |
| Packaging | *Packaged in an Aluminiun tray.* | *Needles are packaged in a polycarbonate tube with end caps placed in a tyvek/mylar pouch and heat sealed.* |

Note: While the template is not supplied sterile is have been validated for efficacy and suitability for autoclave sterilisation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2002

Ms. Linda S. Nash
Corporate Director, Regulatory
Affairs and Quality Systems
Varian Medical Systems
3100 Hansen Way F-055
PALO ALTO CA 94304

Re: K023220
Trade/Device Name: VariSource Breast
Template System
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radio-nuclide
applicator system
Regulatory Class: II
Product Code: 90 JAQ
Dated: September 19, 2002
Received: September 27, 2002

Dear Ms. Nash:

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 (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); 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 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:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

K023320



510(k) Number (if known): K023320

Device Name: VariSource Breast Template System

Indications For Use:

The VariSource Breast Template System is indicated for high-dose rate Brachytherapy irradiation of the breast or chest wall. The system offers a means of performing interstitial implants with a fixed geometry, for the treatment of breast carcinoma. A pair of a series of Templates are fixed in place relative to one another with the Breast Bridge. The Breast Bridge is also used to hold the Templates over the breast during needle insertion and can be adjusted, via a ratchet mechanism to achieve the required template spacing.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

*Prescription Use* /

David A. Segmuller

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023320