

K 123788

**510(k) Summary**  
**SUMMARY OF SAFETY AND EFFECTIVENESS**

JAN 15 2013

**Integrated Conical Collimator Verification and Interlock system (ICVI)**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

**Submitted by:**

Varian Medical Systems, Inc.  
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**Contact Person:** Peter J. Coronado, Director, Regulatory Affairs

**Date summary prepared:** December 7, 2012

**Trade Name:** Integrated Conical Collimator Verification and Interlock system (ICVI)

**Common Name:** Integrated Conical Collimator Verification and Interlock system (ICVI)

**Classification Name:** Medical charged-particle radiation therapy system  
21 CFR 892.5050, Class II  
Product Code: IYE

**Predicate Devices:** SNT Linac Accessories, K971893

**Device Description:**

Integrated Conical Collimator Verification and Interlock system (ICVI) is a secondary collimation system. It also has a security feature that verifies the correct selection of a conical collimator and prevents the radiation treatment device from commencing irradiation when the selected conical collimator is out of conformance with the treatment plan.

Integrated Conical Collimator Verification and Interlock system (ICVI) consists of a collimator mount that attaches to the accessory plate (Slot 2) of the linear accelerator, conical collimators that insert into the mount and are capable of being read electronically by the mount, and a locking ring that locks the conical collimator to the mount.

**Indications for Use:**

The Integrated Conical Collimator Verification and Interlock system (ICVI) is an accessory device indicated for use with a Linear Accelerator to perform Stereotactic Radiosurgery and precision Radiotherapy on intra-cranial and extra cranial lesions or tumors.

**Intended Use:**

The Integrated Conical Collimator Verification and Interlock system is intended for use with a Linear Accelerator to perform Stereotactic Radiosurgery or precision Radiotherapy on intra-cranial and extra cranial lesions or tumors that require a conical collimator to shape the radiation beam.

**Technological Characteristics:**

<b>Characteristic</b>	<b>Predicate Device</b> SNT Linac Accessories, K971893	<b>Subject Device</b> Integrated Conical Collimator Verification and Interlock system (ICVI)	<b>Equivalent or Better?</b>
<b>Intended Use</b>	The SNT Linac Accessories are indicated for use with a Linear Accelerator to perform Stereotactic Radiosurgery or Radiotherapy on cranial lesions. The accessories include a secondary collimation system, components to mount a patient in a stereotactic headring to a linear accelerator's treatment couch, and components to position the patient relative to the isocenter of a linear accelerator in conjunction with a laser alignment system	The Integrated Conical Collimator Verification and Interlock system is intended for use with a Linear Accelerator to perform Stereotactic Radiosurgery or precision Radiotherapy on intra-cranial and extra cranial lesions or tumors that require a conical collimator to shape the radiation beam.	Yes
<b>Indications for Use</b>	The SNT Linac Accessories are indicated for use with a Linear Accelerator to perform Stereotactic Radiosurgery or Radiotherapy on cranial lesions. The accessories include a secondary collimation system, components to mount a patient in a stereotactic headring to a linear accelerator's treatment couch, and components to position the patient relative to the isocenter of a linear accelerator in conjunction with a laser alignment	The Integrated Conical Collimator Verification and Interlock system is an accessory device indicated for use with a Linear Accelerator to perform Stereotactic Radiosurgery and precision Radiotherapy on intra-cranial and extra cranial lesions or tumors.	Yes

	<b>system</b>		
<b>Duration of Use</b>	The patient would usually receive a series of treatments with a linear accelerator.	The patient would usually receive a series of treatments with a linear accelerator.	Yes
<b>Collimator mount</b>	Yes	Yes	Yes
<b>Collimators</b>	Yes, comes with collimators	Yes, comes with collimators	Yes
<b>Design Dimensions</b>	<b>Mount</b> Not published	<b>Mount</b> 476 x 350 x 100 mm without the conical collimator 476 x 350 x 180 mm with the conical collimator	Yes
<b>Design Dimensions</b>	<b>Conical Collimators</b> 118 mm base diameter 73 mm conical collimator diameter 14 mm length	<b>Conical Collimators</b> 118 mm base diameter 73 mm conical collimator diameter 14 mm length	Yes
<b>Design Material</b>	<b>Mount</b> Not published  <b>Conical Collimators</b> Tungsten & Aluminum	<b>Mount</b> Aluminum, Stainless Steel, Brass, Copper, PCB, Cabling  <b>Conical Collimators</b> Tungsten & Aluminum	Yes
<b>Anatomical Sites</b>	Cranial lesions	Intra-cranial and extra-cranial lesions or tumors, benign or malignant	Yes
<b>Mount &amp; conical collimators electronically verifiable</b>	No	Yes	Yes
<b>Provides verification that the correct conical collimator has been selected for patient treatment based on the patient's treatment plan.</b>	No	Yes	Yes
<b>Sterilization</b>	Provided and used non-sterile	Provided and used non-sterile	Yes

Patient Contact	None	None	Yes
Biocompatibility	N/A no patient contact	N/A no patient contact	Yes

**Summary of Performance Testing:**

Testing was performed to demonstrate

- That the device functions correctly with the specified Linear Accelerators
- That the device meets mechanical specifications
- Usability was assessed to the requirements of IEC 62366:2007

Results of verification and validation testing showed conformance to applicable requirement specifications and assured hazard safeguards functioned properly.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-002

Mr. Peter J Coronado  
Director, Regulatory Affairs  
Varian Medical Systems, Inc.  
3100 Hansen Way  
PALO ALTO CA 94304

January 15, 2013

Re: K123788

Trade/Device Name: Integrated Conical Collimator Verification and Interlock System  
(ICVI)

Regulation Number: 21 CFR 892.5050

Regulation Name: Medical charged-particle radiation therapy system

Regulatory Class: II

Product Code: IYE

Dated: December 7, 2012

Received: December 10, 2012

Dear Mr. Coronado:

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. 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); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Janine M. Morris  
Director, Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K123788

Device Name: Integrated Conical Collimator Verification and Interlock System (ICVI)

Indications for Use:

The Integrated Conical Collimator Verification and Interlock system (ICVI) is an accessory device indicated for use with a Linear Accelerator to perform Stereotactic Radiosurgery and precision Radiotherapy on intra-cranial and extra cranial lesions or tumors.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)



(Division Sign Off)

Division of Radiological Health  
Office of *In Vitro* Diagnostic and Radiological Health

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