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

April 2, 2018

Re: K180586
Trade/Device Name: Varian Head Frame
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: March 2, 2018
Received: March 5, 2018

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.

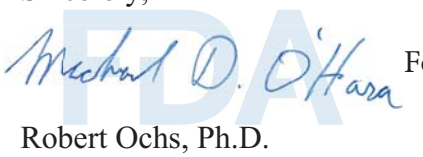
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180586

Device Name
Varian Head Frame

Indications for Use *(Describe)*

The Varian Head Frame System is for use with a computed tomography scanner to perform imaging for treatment planning and a charged particle accelerator to perform immobilization of the treatment target for stereotactic radiosurgery or radiotherapy treatments on cranial lesions, tumors and conditions where radiation treatment is indicated.

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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Premarket Notification [510(k)] Summary

Varian Head Frame

The following information is provided following the format of 21 CFR 807.92(c).

Submitter's Name:	Varian Medical Systems, Inc. 3100 Hansen Way E-110 Palo Alto, CA 94304 Contact Name: Peter J. Coronado Phone: 650.424.6320 Fax: 650.646.9200 Date: March 2, 2018
Name of the Device: Trade/ Proprietary Names:	Varian Head Frame
Classification Name:	Medical charged-particle radiation therapy system 21 CFR 892.5050, Class II Product Code: IYE
Common/Usual Name:	Head Frame
Predicate Device:	Varian Head Frame K142560
Device Description:	The Head Frame provides rigid immobilization of a patient's skull by attaching a rigid halo (head frame) to the patient through four invasive contact points (called screws or pins) which penetrate the patient's skin and contact the bone of the skull. The head frame is secured to either the CT table or the treatment table via a bracket which is included in the system. This ensures the patient cannot easily move during imaging or treatment. This level of immobilization is generally used for stereotactic radiosurgery.
Intended Use Statement	The Varian Head Frame is for use with a charged particle accelerator to perform immobilization of the treatment target for stereotactic radiosurgery or radiotherapy treatments on cranial lesions, tumors and conditions where radiation treatment is indicated.
Indications for Use Statement	The Varian Head Frame System is for use with a computed tomography scanner to perform imaging for treatment planning and a charged particle accelerator to perform immobilization of the treatment target for stereotactic radiosurgery or radiotherapy treatments on cranial lesions, tumors and conditions where radiation treatment is indicated.

Technological Characteristics:

FEATURE AND/OR SPECIFICATION OF NEW/MODIFIED DEVICE	VARIAN HEAD FRAME (v1.0) K142560	VARIAN HEAD FRAME (v2.0)
Indications for use	The Varian Head Frame System is for use with a computed tomography scanner to perform imaging for treatment planning and a charged particle accelerator to perform immobilization of the treatment target for stereotactic radiosurgery or radiotherapy treatments on cranial lesions, tumors and conditions where radiation treatment is indicated.	The Varian Head Frame System is for use with a computed tomography scanner to perform imaging for treatment planning and a charged particle accelerator to perform immobilization of the treatment target for stereotactic radiosurgery or radiotherapy treatments on cranial lesions, tumors and conditions where radiation treatment is indicated.
Intended Use	The Varian Head Frame is for use with a charged particle accelerator to perform immobilization of the treatment target for stereotactic radiosurgery or radiotherapy treatments on cranial lesions, tumors and conditions where radiation treatment is indicated.	The Varian Head Frame is for use with a charged particle accelerator to perform immobilization of the treatment target for stereotactic radiosurgery or radiotherapy treatments on cranial lesions, tumors and conditions where radiation treatment is indicated.
Head Frame Ring	Nickel-plated anodized aluminum	Nickel-plated anodized aluminum
Posts	Material: Delrin	Material: PEEK
CT	CT compatible	CT compatible
Sterilization:	Cleaning for the Head Frame and Posts Autoclave Sterilization for the Cranial Pins only	Cleaning and Autoclave Sterilization for the Cranial pins, Head Frame and Posts

Summary of Performance Testing

Results of verification and validation testing showed conformance to applicable requirements specifications and that the assured hazard safeguards functioned properly. Cleaning, sterilization and reprocessing testing validated the outlined procedures and demonstrated the Head Frame ring can be reprocessed up to 60 cycles and the posts can be reprocessed up to 286 cycles.

Clinical Tests No clinical tests have been included in this pre-market submission

Standards conformance

The Varian Head Frame conforms with the following standards.

IEC 62366:2007
ANSI/AAMI/ISO 10993-1:2009
ANSI/AAMI/ISO 10993-5:2009
AMSI/AAMI/ISO 10993-10:2010
AMSI/AAMI/ISO 10993-11:2010
AAMI TIR12
AAMI TIR30:2011
ANSI/AAMI ST81
ANSI/AAMI ST79
ANSI/AAMI ST35
AAMI TIR34
ASTM E2314-03
ISO 17664
ANSI/AAMI/ISO 17665-1

Conclusions

Based on the verification, validation and non-clinical cleaning and sterilization testing, the Varian Head Frame is as safe and effective and performs at least as well as the predicate device.