K 123808

510(k) SUMMARY

APR 0 4 2013

Date of preparation of summary: 14th February 2013

Submitted by:
Elekta Limited
Linac House, Fleming Way, Crawley, West Sussex
RH10 9RR, United Kingdom
Telephone: +44 (0)1293 654165 Fax: +44 (0)1293 658445

Contact name: Patrick Hull

Trade Name:	Agility™
Common Name:	Multileaf Collimator
Classification Name:	Medical Linear Accelerator Accessory, 21CFR 892.5050
Product Code:	IYE
Predicate Devices:	Agility™ (K121328), Varian RPM (983629), Varian TrueBeam Linear Accelerator (K111106)

Product Description:

This Traditional 510(k) describes changes to the Elekta range of medical linear accelerators when fitted with the Agility multileaf collimator and associated Integrity linac control system. Items added are; High Dose Rate mode x-rays, specific clinical indications for use, and the Response™ gating interface that enables the linac treatment beam to be automatically turned on and off by signals from an external gating device.

High Dose Rate mode x-rays are provided by changes to the filtering arrangement to reduce wasteful attenuation of the beam.

Indications for Use and Intended Use Statement:

The Agility multileaf collimator is indicated for use when additional flexibility is required in conforming the radiation beam to the anatomy to be exposed.

The associated Integrity R3.1 software is the interface and control software for the Elekta medical digital linear accelerator and is intended to assist a licensed practitioner in the delivery of radiation to defined target volumes (e.g. lesions, arterio-venous malformations, malignant and benign tumors), whilst sparing surrounding normal tissue and critical organs from excess radiation.

Both High Dose Rate Mode and flattened beams are intended to be used for single or multiple fractions, delivered as static and/or dynamic, in gated or un-gated deliveries, in all areas of the body where such treatment is indicated.

The use of the Agility multileaf collimator in conjunction with an Elekta digital linear accelerator may be helpful in the delivery of radiation for treatment that includes but is not limited to malignant and benign brain tumors, brain metastases, spine lesions treated using SRS, squamous cell carcinoma of the head and neck, lung, breast, pancreatic, hepatic malignancies treated using SBRT, prostate, and bone metastases.

Summary of Technological Characteristics:

The Elekta range of medical linear accelerators when fitted with the Agility multileaf collimator beam limiting device and its associated linear accelerator control software, Integrity R3.1, and the addition of High Dose Rate mode x-rays and a gating interface do not introduce any novel forms of technology.

Substantial Equivalence

The functionality of the Elekta medical linear accelerator with Agility™ and High Dose Rate mode is substantially equivalent to that of its predicate device, Agility (K1211328), in safety and effectiveness. The intended use, principles of operation, technological characteristics and labeling are substantially equivalent except for the addition of a number of specific indications for use.

Substantial Equivalence Table for High Dose Rate Mode

The primary functional differences between the predicate device and the new device are the changes made to the linac control software and beam filtration to allow the user the option to select unflattened x-ray beams in High Dose Rate mode and the option to fit a gating interface upgrade kit to permit external gating devices to temporarily suspend beam delivery.

Attributes	Elekta linac with Agility, FFF & Integrity R3.1 (this submission)	Varian TrueBeam Linear Accelerator (K111106)
Physics Performance		
Average transmission through leaf bank	<0.375%	Interleaf <2%
Peak transmission through leaf bank	<0.5%	Interleaf <3%
X-radiation leakage in patient plane outside collimator cone	<0.2% max, <0.1% avg.	Information not available
X-radiation leakage outside patient plane	<0.5% (at 1 m)	Information not available
Delivery Techniques		
Dynamic Delivery Capability, sliding window	yes	yes
Dynamic Delivery Capability, Dynamic arc	yes	yes
Dynamic Delivery capability, VMAT	yes	Yes (Rapid Arc)
Multiple island shielding	yes	yes
Offset field shaping	yes	yes
Beam Data – unflattened beams		
6MV - Minimum dose rate	200 MU/min	Not known
6MV - Maximum dose rate	1400 MU/min	1400 MU/min
10MV -Minimum dose rate	400 MU/min	Not known
10MV - Maximum dose rate	2200 MU/min	2400 MU/min

Substantial Equivalence Table for Response Gating Interface

The functionality of the Elekta medical linear accelerator with Agility™ and the Response gating interface is substantially equivalent to that of its predicate device, RPM Respiratory Gating System (K983629), in safety and effectiveness. The intended use, principles of operation, technological characteristics and labeling are substantially equivalent except for the addition of a number of specific indications for use.

Attributes	Elekta linac with Response™ (this submission)	Varian RPM with gating of a Clinac (K983629)
Components		
Control module in the control room for enabling or disabling automated gating and for status review	yes	yes
Relay module on the linac	yes	equivalent
Electrically isolated connection between the Relay module on the linear accelerator and the Control module in the Control room	yes	unknown

Additional features		
Protection for the linear accelerator against rapid gating cycles that may result in delivery of a radiation beam that does not meet IEC specification	yes	unknown
The latency of the signal transmission from the external gating device to operation of the Relay Module	*≤40 ms*	unknown
Automated gating methods supported		
Support external gating device for Respiratory Breath-Hold gating	*yes*	*yes*
Support external gating device for Exception gating	*Yes **	*No***
Support external gating device for Free-Breathing gating	*Yes **	*No ***
Delivery Techniques		
3D Conformal	Yes	Yes
Intensity Modulated Radiation Therapy (IMRT)	Yes	Yes
Image Guided Radiation Therapy (IGRT)	Yes	Yes
Dynamic Delivery Capability, sliding window	Yes	Unknown
Dynamic Delivery Capability, dynamic arc	Yes	Unknown
Dynamic Delivery Capability, VMAT	Yes	Unknown
High Dose Rate (unflattened beams)	yes	Unknown

* *with validated external gating device which has 510(k) clearance*

** *other methods are not supported with the RPM interface*

Summary of non clinical performance testing

Testing in the form of module, integration and system level verification was performed to evaluate the performance and functionality of the new and existing features against the requirement specification.

Regression testing has been performed successfully to verify the integrity of any changes.

Validation of the system under clinically representative conditions has been performed by competent and professionally qualified personnel. Results from verification and validation testing demonstrate that conformance to applicable technical design specifications have been met and assured safety & effectiveness as been achieved.

Testing has been undertaken on production equivalent systems both at Elekta and at hospital sites.

The system is subject to compliance testing to voluntary consensus safety standards. Details of the standards employed in the design are specified in the Standard Data Report in section 9 which includes but is not limited to, IEC 60601-1, IEC 60601-2-1, IEC 62304, IEC 62366 and ISO 14971.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 4, 2013

Patrick Hull
Regulatory Affairs Specialist
Elekta Limited
Linac House
Fleming Way
CRAWLEY, WEST SUSSEX RH10 9RR
UNITED KINGDOM

Re: K123808
Trade/Device Name: Agility™
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: March 6, 2013
Received: March 7, 2013

Dear Mr. Hull:

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" (21CFR 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,

for

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): K123808

Device Name: Agility™

Indications for Use:

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Prescription Use ___YES_ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __NO___ (21 CFR 807 Subpart C)

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

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

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K123808