DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 23, 2017

Synapsys SA
% Ms. Rachel Paul
Senior Consultant, QA & RA
Emergo Europe Consulting
Prinsessegracht 20
The Hague, 2514AP NL

Re: K163558
Trade/Device Name: Synapsys Ulmer Video Nystagmograph
Regulation Number: 21 CFR 882.1460
Regulation Name: Nystagmograph
Regulatory Class: Class II
Product Code: GWN
Dated: March 6, 2017
Received: March 9, 2017

Dear Ms. Paul:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163558

Device Name
Synapsys Ulmer VNG

Indications for Use *(Describe)*
The Ulmer Video Nystagmograph System is intended for use by the physician as an aid for the detection and diagnosis of vestibular disorders. The Ulmer VNG detects and displays eye position and movement in response to a number of vestibular stimulations i.e. saccadic test, smooth pursuit, optokinetic nystagmus, caloric tests and kinetic vestibular tests. The Ulmer VNG records and analyses the bilateral, monocular, horizontal and vertical aspects of eye position and movement. This device is intended to be used in a doctor's office or health care facility to obtain recorded data of nystagmus by directly observing eye motion by video cameras. The resulting recorded data is evaluated by a trained physician and considered along with other relevant data in diagnosing vestibular disorders.

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)

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510(k) Summary (Special 510(k))

Ulmer VNG

K163558

1. Submission Sponsor

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3. Date Prepared

December 16, 2016

4. Device Identification

Trade/Proprietary Name:	Synapsys Ulmer Video Nystagmograph
Common/Usual Name:	Ulmer VNG
Classification Name:	Nystagmograph
Regulation Number:	882.1460
Product Code:	GWN
Device Class:	Class II
Classification Panel:	Neurology

5. Legally Marketed Predicate Device(s)

K982103, Ulmer VNG, Synapsys Incorporated.

6. Indication for Use Statement

The Ulmer Video Nystagmograph System is intended for use by the physician as an aid for the detection and diagnosis of vestibular disorders. The Ulmer VNG detects and displays eye position and movement in response to a number of vestibular stimulations i.e. saccadic test, smooth pursuit, optokinetic nystagmus, caloric tests and kinetic vestibular tests. The Ulmer VNG records and analyses the bilateral, monocular, horizontal and vertical aspects of eye position and movement. This device is intended to be used in a doctor's office or health care facility to obtain recorded data of nystagmus by directly observing eye motion by video cameras. The resulting recorded data is evaluated by a trained physician and considered along with other relevant data in diagnosing vestibular disorders.

7. Device Description

The Ulmer VNG is a video nystagmograph system composed by a software and hardware components.

The software has optional modules: Caloric, Saccade, Slow Pursuit, Kinetic, Optokinetic, Nystagmus (Nystagmus, Gaze or Vertical Subjective modules). It is provided on a CD Rom and activated with a key licensing.

The hardware components correspond to a video acquisition unit. The video acquisition unit is composed by different camera goggles/masks in order to allow the visualization of the movement of one or both eye of the patient. The types of cameras included are as follows:

- Type VNS (goggle camera wired),

- Type WNS (goggle camera wireless using Wifi), and
- Type VISIO (goggle camera for visual free field).

For Kinetic Test, an optional stimulator system can be used and is composed by a speed sensor velocimeter and a rotating chair.

The modified Ulmer VNG system is a modification of the previously cleared Synapsys Ulmer VNG System (K982103) which allows use of a wireless camera (using Wifi).

The advantage of a wireless camera system resides in both ergonomics: manoeuvers made easier without being disturbed by cable presence; and portability: makes possible to bring a VNG system (PC laptop + wireless camera) to the patient unlike other fixed wired systems.

8. Substantial Equivalence Discussion

The following table compares the modified Ulmer VNG to the unmodified predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence, and supports that the subject device, as modified, does not raise any new issues of safety or effectiveness than the predicate device.

Table 5A – Comparison of Characteristics

Manufacturer	**Synapsys SA**	**Synapsys Inc**	**Device Comparison**
Trade Name	**Ulmer VNG**	**Ulmer VNG (Predicate)**	
510(k) Number	Unknown at this date	K982103	N/A
Product Code	GWN	GWN	Same
Regulation Number	882.1460	882.1460	Same
Regulation Name	Nystagmograph	Nystagmograph	Same
Indications for Use	The Ulmer Video Nystagmograph System is intended for use by the physician as an aid for the detection and diagnosis of vestibular disorders. The Ulmer VNG detects and displays eye position and movement in response to a number of vestibular stimulations i.e. saccadic test, smooth pursuit, optokinetic nystagmus, caloric tests and kinetic vestibular tests. The	The Ulmer Video Nystagmograph System is intended for use by the physician as an aid for the detection and diagnosis of vestibular disorders. The Ulmer VNG detects and displays eye position and movement in response to a number of vestibular stimulations i.e. saccadic test, smooth pursuit, optokinetic nystagmus, caloric tests and kinetic vestibular tests. The	Same

Manufacturer	Synapsys SA	Synapsys Inc	Device Comparison
Trade Name	**Ulmer VNG**	**Ulmer VNG (Predicate)**	
	Ulmer VNG records and analyses the bilateral, monocular, horizontal and vertical aspects of eye position and movement. This device is intended to be used in a doctor's office or health care facility to obtain recorded data of nystagmus by directly observing eye motion by video cameras. The resulting recorded data is evaluated by a trained physician and considered along with other relevant data in diagnosing vestibular disorders.	Ulmer VNG records and analyses the bilateral, monocular, horizontal and vertical aspects of eye position and movement. This device is intended to be used in a doctor's office or health care facility to obtain recorded data of nystagmus by directly observing eye motion by video cameras. The resulting recorded data is evaluated by a trained physician and considered along with other relevant data in diagnosing vestibular disorders.	
Mechanism of Action	Eye movements are elicited by visual stimulators then they are recorded and analyzed for detecting nystagmus (involuntary movements of the eyeball) by using a video sensor computer acquisition system. All camera goggles/masks use infrared light.	Eye movements are elicited by visual stimulators then they are recorded and analyzed for detecting nystagmus (involuntary movements of the eyeball) by using a video sensor computer acquisition system. All camera goggles/masks use infrared light.	Same
Technological characteristics	The Ulmer VNG is composed by: -a software with optional modules (caloric, saccade, slow pursuit, kinetic, optokinetic, nystagmus) -a goggle camera: • Type VNS (goggle camera wired) • Type WNS (goggle camera wireless) • Type VISIO (goggle camera for visual free field)	The Ulmer VNG is composed by: -a software with optional module (caloric, saccade, slow pursuit, kinetic, optokinetic, nystagmus) -a goggle camera: • Type VNS (goggle camera wired) • Type VISIO (goggle camera for visual free field)	An additional google camera has been integrated into the system. Contrary to the others existing cameras, this new camera is wireless and uses Wifi connection. The modified Ulmer VNG passed the electrical safety and electromagnetic compatibility testing requirements applicable and the residual risks were found acceptable. The benefits associated

Manufacturer	Synapsys SA	Synapsys Inc	Device Comparison
Trade Name	**Ulmer VNG**	**Ulmer VNG (Predicate)**	
	-an acquisition video system For Kinetic test: Speed sensor and Rotating Chair (optional)	-an acquisition video system For Kinetic test: Speed sensor and Rotating Chair (optional)	with the device excess each of the residual risks.
Configuration	Computer system with basic requirements processor and a Wireless card	Computer system with basic requirements processor	Due to the integration of a wireless camera, a wireless card is needed. The wireless card required in the computer' system configuration does not introduce new risk.
Camera goggles/masks	VNS masks VISIO masks WNS masks	VNS masks VISIO masks	Due to the integration of a new wireless camera, a new WNS mask has been introduced. No new risk was introduced with the WNS mask as the material used in contact with the patient (foam) is unchanged, the infrared LEDs used are the same for a same distance eye/LED. This modification does not raise new questions of safety and effectiveness.
Cameras	Analogic cameras (VNS3X) Numeric cameras (VNS4X) Analog masks (Visio USB 50/100 /200Hz) Wireless cameras (WNS) Battery for Wireless camera	Analogic cameras (VNS3X) Numeric cameras (VNS4X) Analog masks (Visio USB 50/100 /200Hz)	A wireless camera has been introduced into the system. A battery is provided with. The residual risks introduced by the use of a battery were found to be minor and acceptable. The benefits associated with the use of the device exceed this residual risk.
Environment in which Ulmer VNG can be used	-The device must be used in a room suitable for medical examinations.	-The device must be used in a room suitable for medical examinations.	Same

Manufacturer	Synapsys SA	Synapsys Inc	Device Comparison
Trade Name	**Ulmer VNG**	**Ulmer VNG (Predicate)**	
	-Temperature: 10-35°C -Humidity: 30-90% -Pressure: 800-1060 hPa	-Temperature: 10-35°C -Humidity: 30-90% -Pressure: 800-1060 hPa	
Transport and storage conditions	Transport and storage conditions: Storage temperature: -10°C to +55°C Humidity: 10 to 95% Pressure: 700 to 1060hPa	Transport and storage conditions: Storage temperature: -10°C to +55°C Humidity: 10 to 95% Pressure: 700 to 1060hPa	Same
Shelf Life	5 years	5 years	Same
Complies with ISO 10993-1	Yes	Yes	Same
Electrical Safety Testing Passed	Yes	Yes	Same

9. Non-Clinical Performance Data

Electrical safety and electromagnetic compatibility testing and software internal verification confirm that product specifications of the modified Ulmer VNG system are met. These are equivalent to those of the predicate device. The testing results support that the device's change for integration of an additional Wifi camera does not affect the safe and effective use of the device as compared to the unmodified predicate device. Verification testing of the modified Ulmer VNG system, in accordance with design controls, demonstrated the device is safe and effective for its intended use. Verification testing was performed to the following:

- AAMI/ANSI ES 60601-1:2005(R)2012 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- AAMI/ANSI IEC 60601-1-2:2014 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- AAMI ANSI IEC 62304:2006 - Medical device software – Software life cycle processes

The device passed all testing and software verification and is determined to be substantially equivalent to the unmodified Ulmer VNG Synapsys' device.

10. Clinical Performance Data

There was no human clinical testing required to support the medical device as the intended use is the same as the predicate device. These types of devices, including the predicate devices, have been on the

market for many years with proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device; or the device has the same intended use and different technological characteristics, but can be demonstrated to be substantially equivalent to the predicate device, and does not raise additional questions regarding its safety and effectiveness.

As such, the Ulmer VNG System, as modified, is determined to be substantially equivalent to the Synapsys Ulmer VNG predicate device.