August 2, 2018

Qualisys AB
Nils Betzler, PhD
Product Owner
Kvarnbergsgatan 2
Göteborg, 411 05 Se

Re: K171547
Trade/Device Name: Qualisys Clinical System
Regulation Number: 21 CFR 890.5360
Regulation Name: Measuring Exercise Equipment
Regulatory Class: Class II
Product Code: LXJ
Dated: July 2, 2018
Received: July 5, 2018

Dear Dr. Betzler:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171547

Device Name
Qualisys Clinical System

Indications for Use *(Describe)*
The Qualisys Clinical System is a camera and computer system used to quantify and graphically display human movement patterns for adults and children. It is intended to be used for movement analysis in the fields of gait analysis, rehabilitation, sports medicine and ergonomics.

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.

5. 510(k) Summary

Submitter Name and Address

Qualisys AB

Kvarnbergsgatan 2,

SE-411 05 Gothenburg, Sweden

Establishment registration No:

N/A

Contact

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Date Summary Prepared

August 2, 2018

Device Name

Qualisys Clinical System

Common Name

QCS

Classification

Product Code	LXJ
Device Class	2
Regulation Number	890.5360
Review Panel	Physical Medicine

Predicate Device

Name	SMART-D
Manufacturer	BTS SPA, Via della Croce Rossa 11, PD Italy 35129
510(k) Number	K131660
Product Code	LXJ
Device Class	2
Regulation Number	890.5360
Review Panel	Physical Medicine

Device Description

The Qualisys Clinical System (QCS) is a camera and computer system used to quantify and graphically display human movement patterns for adults and children. It is intended to be used for movement analysis in the fields of gait analysis, rehabilitation, sports medicine and ergonomics.

In order to achieve this, the QCS utilizes data captured from image sensors (motion capture cameras) to triangulate the 3D-position of one or several reflective markers attached to the patient. This is done by two or more cameras calibrated to provide overlapping field of views from multiple angles. QCS produce data with 3 degrees of freedom for each marker, i.e. positional information. Rotational information (e.g. of a limb) may be retrieved from the relative orientation of three or more markers.

The tracking cameras may record images and identify the position of the markers with a high spatial and temporal resolution to generate high performance motion capture of the markers.

The markers are usually attached directly to the skin. The markers are specially designed to reflect the IR-light flashed from the tracking cameras.
In addition, subsystems may be added to record data in synchronization with the tracking cameras to facilitate the analysis, or for pure documentation purposes. The additional subsystems may be any one of, or a combination of: 1) Ordinary video, 2) EMG data and 3) Force plate data.

Intended Use

The Qualisys Clinical System is a camera and computer system used to quantify and graphically display human movement patterns for adults and children. It is intended to be used for movement analysis in the fields of gait analysis, rehabilitation, sports medicine and ergonomics.

Substantial Equivalence: The Predicate

Name:	Smart-D
510(k) Holder:	BTS SPA, Via della Croce Rossa 11, PD Italy 35129
510(k) Number:	K131660
Date Cleared:	April 2014

Substantial Equivalence: Technical and functional comparison

The proposed device, Qualisys Clinical System (QCS), is claimed to be substantially equivalent to the predicate SMART-D[K131660].
The comparison of technical and functional characteristics is presented in table 5-1 and table 5-2, respectively. Identified differences are discussed in the next section.

		Name: Qualisys Clinical System **K number: 171547** **Summary: ---**	**SMART-D System** **K number: 131660** **Summary: (Att AD)**	**Eq.**
1	CFR Section	2(*)	2(*)	Yes
2	Product code	LXJ	LXJ	Yes
3	Regulation number	890.5360	890.5360	Yes
4	Classification name	System, optical position/movement recording	System, optical position/movement recording	Yes
5	Intended use	The Qualisys Clinical System is a camera and computer system used to quantify and graphically display human movement patterns for adults and children. It is intended to be used for movement analysis in the fields of gait analysis, rehabilitation, sports medicine and ergonomics.	SMART-D is a system for motion analysis, intended for the recording and analysis of human movement patterns in the fields of rehabilitation, sports medicine, ergonomics.	Yes
6	System Components	Workstation + Software, Tracking Cameras	Workstation + Software, Tracking Cameras	Yes
7	Software Tools	QCS Software modules (QTM, Qualisys Report, Clinical Gait PAF Module) combined with third party "off-the-shelf" software (Visual3D) to achieve: a) Data acquisition b) 3-dimensional marker tracking c) 3D kinematics reconstruction by using an international scientific and validated protocol d) Real-time visualization e) Creating MS Word or Web reports	SMARTcapture, SMARTtracker, SMARTanalyzer, SMARTclinic to achieve: a) Real-time visualization of signals of all integrated devices, b) 3D kinematics reconstruction validated by international scientific community protocols, c) Tool for easy construction of analysis protocols, d) Multimedia customizable and web reporting	No
8	Contraindications	Not needed	Not needed	Yes
9	Target population	All population	All population	Yes
10	Frame rate	100 fps	200 fps	No
11	Acquisition Frequencies	500-1500 HZ (dependent on source)	250 Hz (up to 500 Hz)	No
12	Light emission	Infrared	Infrared	Yes
13	Light wave length	850 nm	880 nm	No
14	Output Angle	61-42 degree (FOV)	40 degree	No

15	Modulation / External Sync	Y	Y (Square wave synchronized with the acquisition frequency)	Yes
16	Lens	C-mount	C-mount	Yes
17	Number of Cameras	up to 100	up to 16 digital TVC	No
18	Camera resolution	1216×800 - 4096×3072	800 H x 600 V	No
19	3D Trajectory Reconstruction	Y (QTM)	Y (SMARTtracker)	Yes
20	Customizable Analysis Protocol	N (PAF)	Y (SMARTanalyzer)	No
21	Reporting	Y (Qualisys Report Generator)	Y (SMARTclinic)	Yes
22	Weight	1 kg / camera	20 kg	No
23	Dimension	140*87*84 mm (camera)	450*330*500 mm	No
24	Realtime visualization	Y	Y	Yes
25	Max input power	Max 30W / camera. To be scaled accordingly to number of cameras used.	950 W	No
26	Power supply	110 V, 60 Hz / 230 V, 50 Hz Dual power.	110 V, 60 Hz	Yes
27	Electrical Safety	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012	AAMI/ANSI ES60601-1:2005 and further amendments	Yes
28	EMC	IEC-60601-1-2	IEC 60601-1-2	Yes
29	Options	None	None	Yes

Tabell 5-1 Technical Characteristic Comparison. Note Eq – Equivalent. * - previously unclassified

	Functionality Characteristics	**Qualisys Clinical System K number: 171547 Summary: ---**	**SMART-D System K number: 131660 Summary: (Att AD)**	**Eq.**
1	Calibration and Signals acquisistion	Real-time visualization of all acquired data using Qualisys QTM and "Clinical Gait PAF Module"	SMARTcapture: a) Real-time visualization of signals of all integrated devices	Yes
2	Trajectory reconstruction, signal elaboration	3D marker trajectory evaluated by the Qualisys QTM software module. Marker mapped to an anatomical human model by a scientific international validated protocol	SMARTtracker: b) 3D kinematics reconstruction validated by international scientific community protocol	Yes
3	Management of acquired data customizable analysis protocols	Predefined analysis protocol	SMARTanalyzer: c) Tool for easy construction of analysis protocols	No

4	Report drafting, data visualization	Visualization tool to verify the trajectories and anatomical mapping algorithm. Graphical presentation in Reports	SMARTclinic: d) Multimedia customizable and web reporting	Yes

Tabell 5-2 Functional Characteristic Comparison. Note Eq – Equivalent.

Substantial Equivalence: Discussion of technical and functional differences

The identified technical and functional differences (table 5-1 and table 5-2) are discussed below in table 5-3 and table 5-4, respectively.

Technical Characteristics	**Qualisys Clinical System K number: 171547 Summary: ---**	**SMART-D System K number: 131660] Summary: (Att AD)**
Software Tools	QCS Software modules (QTM, Qualisys Report, Clinical Gait PAF Module) combined with third party "off-the-shelf" software (Visual3D) to achieve: a) Data acquisition b) 3-dimensional marker tracking c) Mapping marker movement to a body-model using a international scientific protocol. d) Creating MS Word or Web reports	SMARTcapture, SMARTtracker, SMARTanalyzer, SMARTclinic to achieve: a) Real-time visualization of signals of all integrated devices, b) 3D kinematics reconstruction validated by international scientific community protocols, c) Tool for easy construction of analysis protocols, d) Multimedia customizable and web reporting
The QCS and its predicate perform the same tasks. Acquire data, reconstruct 3D-marker positions/trajectories, mapping data to a human anatomical body to extract kinematic information and creating reports		
Frame rate	100 fps	200 fps
Whilst all of the supported Qualisys motion capture camera models are capable of operating at higher frame rates, Qualisys recommends a frame rate of 100 fps for gait analysis. This is in line with recommendations from the scientific literature: • *Baker (2013, p. 210): "Most current systems can capture at 100 – 120 Hz, which is more than adequate for clinical gait analysis (although faster sample rates may be required for running)."* • *Richards (2008, p. 108): "Cameras exist that can provide sampling frequencies up to 10 kHz, but it is well accepted that 50 Hz is adequate for studying many aspects of human walking."* • *Stergiou (2004 p. 236): recommended sampling frequencies for walking are 50 to 100 Hz for motion capture.* *This will not influence intended use or reduce safety or effectiveness of the QCS compared to the predicate.* *Full references:* *Baker, Richard (2013): Measuring Walking: A Handbook of Clinical Gait Analysis. 1st Edition. London: Mac Keith Press.*		

Richards, Jim (2008): Biomechanics in Clinic and Research. 1st Edition. London: Churchill Livingstone. Stergiou, Nicholas (2004): Innovative Analyses of Human Movement. Champaign, IL: Human Kinetics.		
Acquisition Frequencies	500-2000 Hz (dependent on source)	250 Hz (up to 500 Hz)
QCS will record analog data faster than the predicate. This improves the time-resolution and will therefore not influence intended use or reduce the safety or effectiveness of the QCS compared to the predicate		
Light wave length	850 nm	880 nm
The IR wavelength is close to be the same and both are well within the range of IR-light. From a practical point of view, the IR-light from the two systems behave the same in terms of attenuation and scatter. Further the QCS-cameras are optimized to work at this specific wavelength. There is no influence on Intended use or reduction of safety and effectiveness due to the slight difference in IR wave length		
Output Angle	61-42 degree (FOV)	40 degree
The QCS has a wider Field of View (FOV) than the predicate. This allows the QCS to detect reflective markers over a wider spatial region which in turn will improve marker detectability. There is no influence on Intended use or reduction of safety and effectiveness due to the wider FOV		
Number of Cameras	up to 100	up to 16 digital TVC
The QCS supports more cameras than the predicate. Does not influence the Intended use or reduce the safety or effectiveness		
Camera resolution	1216×800 - 4096×3072	800 H x 600 V
The QCS system has a higher image resolution than its predicate. This will improve the precision of the marker detection and/or improve the detection distance from the camera compared to the predicate. Will not influence the "Intended use" or reduce the safety or effectiveness		
Customizable Analysis Protocol	N (PAF)	Y (SMARTanalyzer)
The QCS does not allow the user to modify the analysis protocol. The protocol is considered to be a crucial part of the software, requiring specific verification and validation. As such, this does not influence the "Intended use", impose any risk or reduced safety or efficiency.		
Weight	1 kg / camera	20 kg
The QCS does not require a base station, instead the sub-systems are directly connected to the PC workstation. The weight of a camera does not bring a point of non-substantial equivalence between the QCS system and its predicate. The difference in weight does no influence the "Intended use" or reduce the safety or the effectiveness		
Dimension	140*87*84 mm	450*330*500 mm
The dimensions of a camera do not constitute a point of non-substantial equivalence between the QCS system and its predicate. The difference in dimensions does no influence the "Intended use" or reduce the safety or the effectiveness		

Max input power	Max 30W / camera. To be scaled accordingly to number of cameras used.	950 W
The max input power does not constitute a point of non-substantial equivalence between the SMART-D System and the predicate devices, as it does not influence the intended use, the performance, the safety and effectiveness of the system than the predicate devices		

Tabell 5-3 Technical Characteristic Differences Discussion.

Functionality Characteristic	**Qualisys Clinical System K number: 171547 Summary: ---**	**SMART-D System K number: 131660 Summary: (Att AD)**
Management of acquired data customizable analysis protocols	Predefined analysis protocol	SMARTanalyzer: c) Tool for easy construction of analysis protocols
The QCS does not allow the user to change the analysis protocol. The reason for this is that the protocol is considered to be a crucial part of the software and the corresponding verification and validation of the software. The quality of its design is considered an integral part of the system. This does not influence the "Intended use", impose any risk or reduction on safety or on efficiency		

Tabell 5-4 Functionality Characteristic Differences Discussion.

Performance Data

Non-clinical tests performed on the QCS include software and hardware tests. All software tests passed successfully, demonstrating that the QCS meets all specified requirements. Hardware has been tested successfully for EMC compatibility (IEC-60601-1-2), and electrical safety has been assessed and found to comply with a relevant standard (ANSI AAMI ES60601-1), which is equal to the standard used by the predicate. Metrological accuracy and reliability of the raw output of the system (three-dimensional position of reflective markers) has been verified and validated, and the dimensions of the calibration devices supplied with the system are traceable to a national meter reference. Further, a Clinical Evaluation report has been provided, supporting the clinical relevance of gait assessments.

Conclusion

Based on the comparison, discussion of identified differences and test results, it is concluded that the proposed device (Qualisys Clinical System) is substantially equivalent to its predicate (SMART-D[K131660]).