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

July 26, 2017

MedCom GmbH
% Mr. Johannes Messow
Quality Manager
Dolivostrasse 11
Darmstadt, Hessen 64293
GERMANY

Re: K170841
Trade/Device Name: BiopSee, Mobile US
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 21, 2017
Received: June 26, 2017

Dear Mr. Messow:

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170841

Device Name
BiopSee, Mobile US

Indications for Use *(Describe)*
The BiopSee bundled system is a combination of MobileUS providing the "Medical Image Processing Workstation" which acquires and displays ultrasound images from external ultrasound scanners and the BiopSee "Image Fusion Navigation Software" which is a stereotaxic accessory for Ultrasound (US) devices.
The BiopSee system is intended to be used in clinical interventions and for anatomical structures in a clinical setting where US imaging is currently used for visualizing such procedures. It displays the simulated image of a tracked insertion tool such as a biopsy needle on a computer monitor that shows images of the target organs and the current and the projected future path of the interventional instrument.
The patient population is mainly people who need prostate biopsy.
It is intended to be used mainly in the Urological departments for prostate biopsies.

The BiopSee system is not intended to be used as a standalone diagnostic image device, since it represents information of a patient that could not be congruent with the current (actual) patient position and shall therefore always be seen as an additional source of information.
The BiopSee system when connected with an electromagnetic tracker should not be used on or around persons with a cardiac pacemaker, and should not be used around life supporting equipment.
BiopSee is a prescription device.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

III. 510(k) Summary of Safety and Effectiveness

A. Submitter

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Contact:	Mr. Johannes Messow jmessow@medcom-online.de
Date:	March 27, 2017

B. Device

Trade Name:	BiopSee	MobileUS
Common name**:**	BiopSee, BiopSee System	MobileUS, MobileUS Stand-Alone

Classification:	Regulatory Class:	II
	Product Code:	LLZ / Classification Name: System, Image Processing, Radiological
	CFR Section:	892.2050
	Panel:	Radiology

C. **Predicate Devices**

BiopSee:

Device trade name:	MIM 3.5 (CIRCA)
510(k) number:	K052379
Company name:	MIMVISTA CORP.
Classification Number:	892.2050
Classification:	Class II
Product code:	LLZ

Device trade name:	UroNav Fusion Biopsy System
510(k) number:	K153073
Company name:	Philips Medical Systems International BV
Classification Number:	892.2050
Classification:	Class II
Product code:	LLZ

Device trade name:	NaviSuite SSI Edition
510(k) number:	K163119
Company name:	MedCom GmbH.
Classification Number:	892.2050
Classification:	Class II
Product code:	LLZ

MobileUS:

Device trade name:	UroNav Fusion Biopsy System
510(k) number:	K153073
Company name:	Philips Medical Systems International BV
Classification Number:	892.2050
Classification:	Class II
Product code:	LLZ

Device trade name:	Oncentra Prostate 4.0
510(k) number:	K112420
Company name:	Nucletron Corporation
Classification Number:	892.5700
Classification:	Class II
Product code:	JAQ

Device trade name:	NaviSuite SSI Edition
510(k) number:	K163119
Company name:	MedCom GmbH.
Classification Number:	892.2050
Classification:	Class II
Product code:	LLZ

D. **Reason for Submission**

New device application

E. **Standards**

1. ISO 14971:2007, Medical devices - Application of risk management to medical devices. (General I (QS/RM))

2. IEC 62304:2006, Medical Device Software - Software Life Cycle Processes. (Software/Informatics)

3. IEC 60601-1:2005/A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

4. IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests

F. **Description**

The BiopSee bundled system (also called BiopSee System) is a medical image processing workstation that provides image guided instrument navigation. The hardware part (MobileUS) consists of the system unit which includes a CPU, a monitor, medical-grade keyboard, mouse and power supply and a medical trolley. It is designed to display ultrasound images from different sources. Optionally it can be equipped with an electromagnetic positioning system to track the ultrasound probe or other medical instruments.

The system is able to load different image modalities such as Magnetic Resonance Imaging (MRI), Computed Tomography (CT), Positron emission tomography (PET) and allows organ delineation and planning instrument access paths within the 3D dataset. It is designed to display 2D images from commercially available ultrasound systems and either reconstruct a 3D ultrasound image or fuse the images with pre-loaded other datasets.

The BiopSee software can be installed on standard PCs under Microsoft Windows operating systems which follow the minimum requirements described in the service manual, similar to MobileUS hardware. BiopSee is designed to work in combination with an ultrasound scanner (the Ultrasound System is used in order to display the live US images) and a probe, a positioning system (to track the position of the probe) and medical navigation instruments (to track the position of the medical instruments like needles). The ultrasound scanners connected must be tested with the BiopSee System and shall be legally marketed in the US.

Examples of compatible devices are:

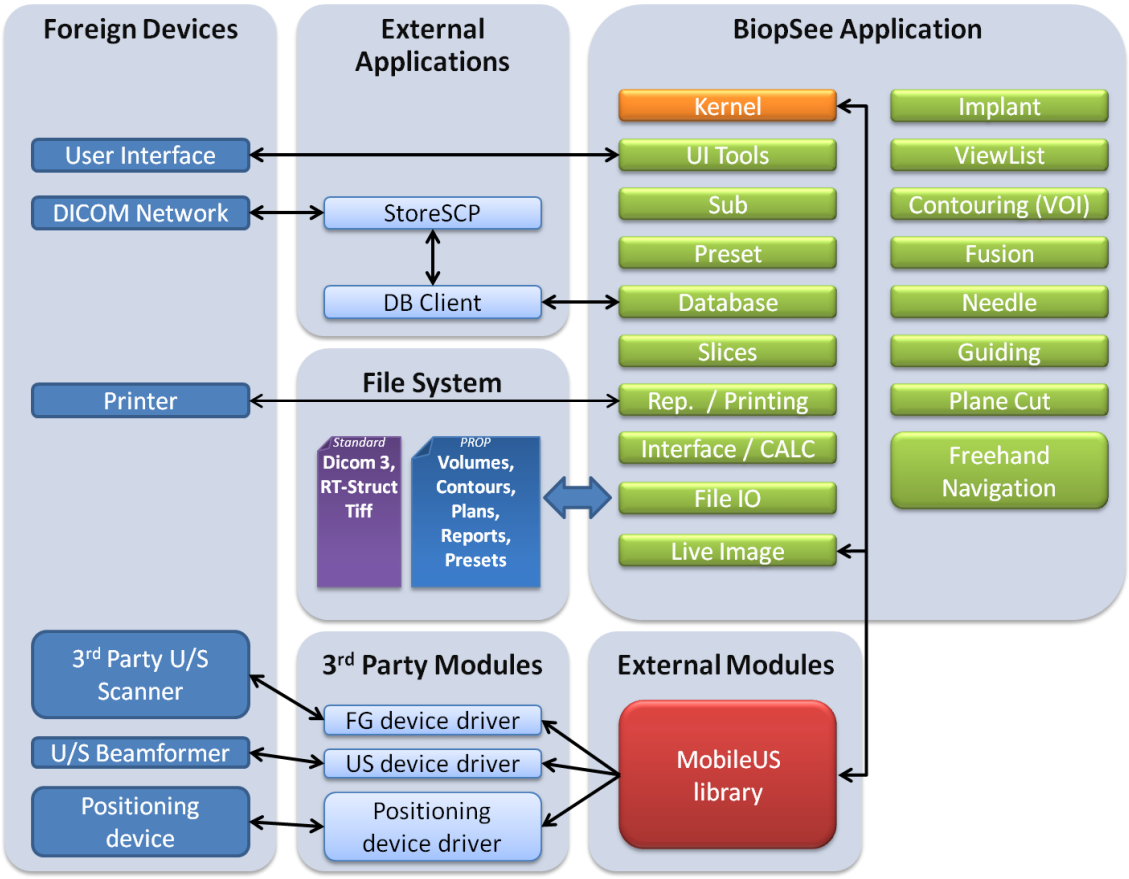
Device	Type	510(k) / registration number
System, Imaging, Pulsed Doppler, Ultrasonic	HITACHI Noblus	K160559
	BK 2300	K151910
	Supersonic AIXPLORER	K142100
	ESAOTE 6200 My Lab	K153277

It can also be connected to a commercially available mechanical stepper in order to acquire the precise position of the ultrasound probe. Alternatively an Electromagnetic Measurement System (EMMS) can be integrated in the MobileUS hardware (or equivalent) to accurately track the position of the ultrasound probe.

Within BiopSee, one is able to: acquire, process and display ultrasound images and create 3D volumes out of 2D image sequences. The software is also capable of loading and displaying 3D DICOM 3 image series.

In more details the system allows organ delineation and planning instrument access paths within a 3D dataset. To enhance the procedure planning the user can load multiple datasets and perform image fusion.

During the navigation procedure, the system displays live ultrasound image overlaid by the planning objects, thus guiding the user through medical instrument placement at the intended position. The planned access paths and targets can be updated reflecting the real situation for proper documentation. The physician can attach a commercially available biopsy needle guide to the ultrasound probe and use it in combination with a prostate biopsy needle to perform tissue biopsy. Similarly the physician can attach a template needle guide to the stepper in order to insert prostate biopsy needles to the desired positions.



System Overview

G. Intended Use

The BiopSee bundled system is a medical imaging workstation for medical professionals, which is designated to support image guided instrument navigation. Additionally, the BiopSee software can be used for a general ultrasound examination.

Within BiopSee, one is able to: acquire, process and display ultrasound images and create 3D volumes out of 2D image sequences. The software is also capable of loading and displaying 3D DICOM 3 image series.

The system allows organ delineation and planning instrument access paths within a 3D dataset. To enhance the procedure planning the user can load multiple datasets and perform image fusion.

During the navigation procedure, the system displays live ultrasound image overlaid by the planning objects, thus guiding the user through medical instrument placement at the intended position. The planned access paths and targets can be updated reflecting the real situation for proper documentation.

BiopSee runs on standard PCs under Microsoft Windows operating systems. It is designed to work with compatible commercially available ultrasound scanners and probes, positioning systems and medical navigation instruments.

H. Indications for Use

The BiopSee bundled system is a combination of MobileUS providing the “Medical Image Processing Workstation” which acquires and displays ultrasound images from external ultrasound scanners and the BiopSee “Image Fusion Navigation Software” which is a stereotaxic accessory for Ultrasound (US) devices.
The BiopSee system is intended to be used in clinical interventions and for anatomical structures in a clinical setting where US imaging is currently used for visualizing such procedures. It displays the simulated image of a tracked insertion tool such as a biopsy needle on a computer monitor that shows images of the target organs and the current and the projected future path of the interventional instrument.
The patient population is mainly people who need prostate biopsy.
It is intended to be used mainly in the Urological departments for prostate biopsies.

The BiopSee system is not intended to be used as a standalone diagnostic image device, since it represents information of a patient that could not be congruent with the current (actual) patient position and shall therefore always be seen as an additional source of information.
The BiopSee system when connected with an electromagnetic tracker should not be used on or around persons with a cardiac pacemaker, and should not be used around life supporting equipment.
BiopSee is a prescription device.

I. Technological Comparison to Predicate Devices

The device BiopSee is substantially equivalent to the following predicate devices:

K052379	MIM 3.5 (CIRCA)
K153073	UroNav Fusion Biopsy System
K163119	NaviSuite SSI Edition

The predicate device MIM 3.5 (CIRCA) has the same main functionalities and characteristics as BiopSee for both transrectal and transperineal approaches and uses also commercially available electronic stepper and electromagnetic tracking devices.

The predicate device UroNav (Version 2.0) and BiopSee are adequately similar, with the exception of the transperineal version of BiopSee, having the same intended use as well as the same main functionalities and characteristics. The difference in the transperineal version of BiopSee is that an electronically tracked stepper is used whereas UroNav uses an electromagnetically tracked stepper.

The software of the predicate device NaviSuite is also developed by MedCom, and includes the main functionalities for tracked needles version.

Refer to section X for a detailed predicate device comparison.

The device MobileUS is substantially equivalent to the following predicate devices:

K153073	UroNav Fusion Biopsy System
K112420	Oncentra Prostate 4.0
K163119	NaviSuite SSI Edition

The predicate device UroNav Fusion Biopsy System is substantially equivalent with MobileUS since it is a mobile computer workstation, a commercially available navigation device and software with functions that are commonly found in various medical imaging applications. The MobileUS is similar to UroNav since it does not directly contact the patient, nor does it control any life sustaining devices. Diagnosis is not performed by the MobileUS system but by Radiologists, Urologists, Clinicians and referring Physicians.

The predicate device Oncentra Prostate 4.0 encompasses the majority of the MobileUS functionality. Actually MobileUS is a small subset of Oncentra prostate, in particular: ultrasound image display, encoder status and position display and grid overlay display. Therefore they are adequately similar. The exception is support for electromagnetic tracking which Oncentra Prostate doesn't have.

The predicate device NaviSuite SSI Edition has similar functionality with respect to displaying ultrasound image and processing data from the electromagnetic tracking system. The functionality of MobileUS is a subset of that of NaviSuite SSI Edition. Both systems use similar tracking hardware from the same manufacturer.

Refer to section X for a detailed predicate device comparison.

J. Non-clinical Performance Data

Non-clinical verification and validation software tests were conducted to confirm that the BiopSee System meets its intended use and is safe and effective.

System Accuracy Test:
The software cannot determine the accuracy of the treatment procedure. The Therapist or Physician is responsible for verifying the correctness of the registration. For this means the software offers side by side and overlay views (with a real-time US image).

Integration testing for needle navigation using CIRS Phantoms to confirm the software projected virtual needle position over the real time US image, showed accuracy with an overall error better than 5 mm.

Tracking Quality Test:
The system can detect low sensor tracking quality and is able to show if the tracking is distorted (for example by metallic objects etc.).

Tests for verifying the tracking accuracy and sensor in range status have been carried out during Integration tests.

The BiopSee system uses an integrated “Ascension 3D Guidance trakSTAR” as electromagnetic guidance system.

Statement: The accuracy for the electromagnetic guidance system “Ascension 3D Guidance trakSTAR” is stated by it manufacturer NDI Europe with:
Accuracy: 1.4 mm RMS, 0.5 degrees RMS

System Accuracy

2nd Modality Image Display

The system accuracy concerning the matching between the ultrasound image and the 2nd modality image depends highly on the registration process and the condition of the patient compared to the situation when the 2nd modality (i.e. the CT scan) has been acquired.

However, from the technical point of view an “overlapping” accuracy of at least 5mm can be achieved under the presumption that the registration has been done with an overall error better than 5mm.

Length measurement (Ruler Function)
In the ultrasound image: 5% error, or better.
In the 2nd modality image: 5%-10%, or better. Please note that this value depends on the quality of the 2nd modality dataset.

K. **Conclusion**

Based on the information provided in this Premarket Notification MedCom concludes that BiopSee bundled system is as safe and effective and substantially equivalent to the predicate devices described herein.