K100204

510(k) Summary

807.92(c)

FEB 19 2010

SPONSOR **807.92(a)(1)**

Company Name:	Best NOMOS
Company Address	One Best Drive Pittsburg, PA 15202
Telephone:	(800) 70-NOMOS
Contact Person:	Andrew Chi Palko

Summary Preparation Date: November 24, 2009

DEVICE NAME **807.92(a)(2)**

Trade Name:	Sonalis® Ultrasound System
Common/Usual Name:	Diagnostic Ultrasound System
Classification Name:	Ultrasonic pulsed echo imaging system, Diagnostic ultrasonic transducer
Regulation Number:	892.1560, 892.1570
Product Code:	IYO, ITX
Device Class:	Class II

PREDICATE DEVICE **807.92(a)(3)**

Legally Marketed Equivalent Device

Company	*Product*	*510(k) #*
3G Ultrasound Inc.	Sonalis Ultrasound System	K043189

DEVICE DESCRIPTION **807.92(a)(4)**

The SONALIS® is a real time, two-dimensional, diagnostic system that produces high quality images. The system currently supports imaging applications for trans-rectal ultrasound imaging. The system consists of:

- system console,
- keyboard,
- ultrasound probe,
- ultrasound probe connector,
- power cord,
- high resolution LCD monitor to display the image,
- System Operating Manual
- B&W graphic printer

DEVICE INTENDED USE **807.92(a)(5)**

The SONALIS® system and transducers are intended for diagnostic ultrasound imaging of the human body. The clinical application is trans-rectal imaging. Typical examination using the SONALIS® Platform system: Prostate and Rectal wall studies.

COMPARISON OF TECHNICAL CHARACTERISTICS **807.92(a)(6)**

This device operates identically to the predicate device in that the piezoelectrical material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as a 2D images.

NONCLINICAL AND CLINICAL TEST **807.92(b)**

SAFETY and EFFECTIVENESS

The SONALIS® is compliant to the safety standards.

UL60601-1 (2003), 1st Edition Medical Electrical Equipment, Part 1, General Requirements for Safety

IEC 60601-1 (1988), 2nd Edition, Medical Electrical Equipment, Part 1: General Requirements for Safety +A1(91) + A2(95)

IEC 60601-2 (2001), 2nd Edition Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic compatibility

IEC 60601-2-37 (2001), 1st Edition Medical Electrical Equipment Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment +A1(2004)

BIOCOMPATIBILITY

SONALIS® was tested in accordance with the testing requirements of the ISO 10993 Recognized Standards and found to be safe for its intended use.

CONCLUSION **807.92(b)(3)**

The SONALIS® Ultrasound System is the same device as the predicate except for updated components that do not affect safety and efficacy. The SONALIS® Ultrasound System is the same device

- Intended Use
- Design
- Technological Characteristics

The Sonalis Ultrasound System introduces no new questions concerning the safety or effectiveness and is thus substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Best NOMOS
% Mr. Ned Devine
Senior Staff Engineer
Underwriters Laboratories, Inc.
333 Pfingsten Road
NORTHBROOK IL 60062

FEB 19 2010

Re: K100204
Trade/Device Name: SONALIS
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: January 15, 2010
Received: January 22, 2010

Dear Mr. Devine:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100204

Device Name: SONALIS

Indications for Use:

The SONALIS® system and transducers are intended for diagnostic ultrasound imaging of the human body. The clinical application is trans-rectal imaging.

Typical examination using the SONALIS® Platform system: Prostate and Rectal wall studies.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K100204

TRACK 1

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P								
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Sonalis TRT TRIVIEW -467

(Division Sign-Off)

Division of Radiological Devices

Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K100204