510(K) SUMMARY
[As Required by 21 CFR 807.92]

1	Submitter's information	ODVI 20 rue de la Croix Nivert 75015 Paris France Phone and fax number : (+33) 1 43 06 10 18 Contact person : Dr Herve BINDEFELD, Technical and Scientific Director
	Preparation date of the summary	December, 19th 2005
2	Name of the device	Acoustic and doppler stethoscope Stethoflux©
	Code product	KNG
	Classification	Monitor, blood flow, class II according to 21CFR 884.2660 884.2660 Fetal ultrasonic monitor and accessories
3	Predicate substantially equivalent device	K030466, HandyDop TM, Etcat GmbH
4	Description of the device	Acoustic stethoscope with ultrasonic transducer
	Concept	
	Explanation of how the device operates	It operates with 2 modes : stethoscopic mode (classical stethoscope) and Doppler mode
	Physical and performance characteristics	Powered by one (6LR61) 9V lithium battery Doppler frequency : 8 MHz Operating time : 25 h according to use Mass : 331 g
	Differences from predicate devices	A single probe 8 MHZ which is built-in the housing : instead of 3 which are connected A single battery instead of 2 rechargeable batteries
5	Intended use	Detection and listening of the blood-flow in the peripheral vascular system The Stethoflux© is designed for use by general practitioners or specialists on their own responsibility. It allows dual stethoscopic and doppler peripheral vascular investigation in a simple auscultation.
	Conditions that the device diagnoses	Classical clinical investigation - It allows dual stethoscopic and Doppler vascular investigation in a single examination, facilitating the detection of blood-flow When associated with a sphygmomanometer, Systolic Blood Pressures (SBP) measurement of the lower limb and upper-limb in order to determine the possible PAD in the concerned limb
	Troubles and diseases	Cardiovascular diseases such as atherothrombosis and Peripheral Artery Diseases (PAD)

	Target patient population	Everybody, mainly patients having cardiovascular risk
	Target users population	dedicated to physicians specialised in vascular pathology : general practitioners or specialists on their own responsibility
	Examination sites	Standard acoustic examination : heart, lungs, abdomen, arteries Doppler examination of the peripheral vessels, mainly brachial artery and posterior tibial, anterior tibial or dorsalis pedis arteries Non invasive device
	Differences of the indication statements from predicate device	None for the common application with the 8 MHz probe
	Explanations arguing that they are minor	The differences concern the presentation of the device, such as the built-in probe and battery number. They do not affect the safety and effectiveness of the device.
6	Comparison between predicate device specifications and those of the Stethoflux®	Similar specifications for the common application with the 8 MHz probe
7	Performance data	There are no section 514 performance standards for this class of device for assisting in the determination of its substantial equivalence.
	Conclusions drawn from clinical and non clinical test data	Not required for determination of substantial equivalence for this class of device, though publication of some clinical data are contained in this premarket submission
	Substantial equivalence summary	Stethoflux© is comparable and substantially equivalent to the legally marketed predicate device concerning the 8 MHz mode. The intended use is the same as that of the predicate devices. The subject device has substantially equivalent technological characteristics, features, specifications, materials, mode of operation, and intended use as a legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 1 0 2006

OVDI
% Mr. Armelle LAPRELLE
Project Leader
CEISO
69 rue de Paris
91400 Orsay
FRANCE

Re: K060064
Trade Name: Stethoflux®
Regulation Number: 21 CFR 892.1540
Regulation Name: Nonfetal ultrasonic monitor
Regulatory Class: II
Product Code: JAF
Dated: December 29, 2005
Received: January 9, 2006

Dear Mr. LAPRELLE:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the Stethoflux® and 8 MHz CW Split Crystal transducer as described in your premarket notification.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your 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 market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Andrew Kang, M.D. at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

4.3 - INDICATIONS FOR USE

510(k) Number (if known): K060064

Device Name: Stethoflux®

Indications for Use: Diagnostic ultrasound blood flow detection of the human body

The Stethoflux® is designed for use by general practitioners or specialists on their own responsibility. It allows dual stethoscopic and doppler peripheral vascular investigation in a simple auscultation.

It facilitates :
- the detection of blood-flow in the peripheral arteries
- Systolic Blood Pressures (SBP) measurements of the lower limb and upper-limb in order to determine the possible PAD ankle Brachial index (ABI) in the concerned limb, when associated with a sphygmomanometer

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060064

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM
(as required in appendix F of the FDA Guidance)
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 Doppler	Color Velocity Imaging	Combined (specify)	Other (specif)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular					N					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skele tal Superficial										
Other (specify)										

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

Additional Comments: The Stethoflux includes a 8 MHz unfocused CW transducer, indicated for the detection of the blood-flow in the peripheral vessels

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Concurrence of CDRH, Office of Device Evaluation (ODE)
510(k) Number K060064

Prescription Use (Per 21 CFR 801.109)