JUN - 8 1998

510(k) SUMMARY

This summary of 510(k) Safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K974880.

1. Submitter's Identification :

Perception Inc.
9344 N.W. 13th Street, Suite 200
Miami, Florida 33172
Contact Person : Mr. Jorge Millan

Date Summary Prepared: December 5, 1997

2. Name of the Device :

Perception GPS-RST Diagnostic Ultrasound System

3. Predicate Device Information :

1. **Aloka Co.**
   Model SSD-1700 K963616

2. **Diasonics Ultrasound**

Models	Synergy	K935024
	CFM800	K924079
	EchoPac	K962662

3. **Perception Inc.**
   Model GPS-TUV K#972973.

4. Device Description :

General Description

The Perception's GPS-RST Ultrasound System is a PC (computer) based and controlled real time, two dimensional, mechanical sector and electronic array diagnostic ultrasound and pulsed Doppler imaging system which produces diagnostic ultrasonic images and blood flow spectral analysis through user friendly operation.

The following intended uses are identified for the transducer applications: General radiology, Abdominal, Cardiac and Vascular, with the use of

ultrasonic probes from 3.0-12.5 MHz. There are no transcranial applications for this device.

User interface is via an alphanumeric keypad, trackball and Icon-driven graphical interface. The Perception Inc. GPS-RST Diagnostic Ultrasound System may be operated in M /B /D modes of inspection. The Perception GPS-RST Diagnostic Ultrasound System supports M, B, M&B, Dual B, Quad B, D and D/B, display modes.

All probes currently intended for use with the Perception GPS-RST Diagnostic Ultrasound System are either mechanical sector devices or electronic linear array, and make use of a fluid filled design. Transducer parameters are summarized in the following table:

PROBE	CENTER FREQ	TYPE	INSP.MODES	APPLICAT.
GP-3.0	2.8 MHz	MECH.SEC	M/B/D	Gen.Purpose/ Abdominal/ Cardiac
LA-7.5	7.5 MHz	LINEAR.ARR	M/B/D	Peripheral Vascular
PV-12.5	12.5 MHz	MECH SEC	M/B	Peripheral Vascular

5. **Intended Use:**

See Attachment.

6. **Comparison to Predicate Devices:**

We believe the Perception Inc. GPS-RST Diagnostic Ultrasound System to be substantially equivalent to ultrasound devices currently in commercial distribution in the U.S. A table of comparison outlining similarities and differences between the Perception Inc. GPS-RST Diagnostic Ultrasound System and predicate devices is attached to this summary.

7. **Discussion on Non-Clinical Test Performed for Determination of Substantial Equivalence are as Follows:**

This 510(k) submission is intended as a Track 1 type submission. Acoustic Output Reporting was prepared utilizing the following documents.

- NEMA 1992, Acoustic output measurement standard for diagnostic ultrasound equipment, NEMA Standard UD-21992.

- FDA Center for Devices and Radiological Health 1985 510(k) Guide for Measuring and Reporting and Acoustic Output of Diagnostic Ultrasound Medical Devices, December, 1985, Revised, 1989, 1990, 1991,1993, 1994, and 1995.

Acoustic output of each system/transducer/mode/application combination was measured and calculated per the above documents. The following testing was conducted which revealed satisfactory testing results and compliance to applicable standards.

- Maximum Acoustic Output Information
- Estimated In-Situ Intensity
- FDA In-Situ Intensity Limits
- Acoustic Output Information for each system/transducer/mode combination

The following testing was conducted by a contract testing laboratory:

- UL-544, Third Edition
- Radiated and Conducted Emissions per CISPR 11
- Magnetic Field Emissions per MIL-STD-482D, method RE101
- Electrostatic Discharge Immunity per IEC 801-2
- Radiated Field Immunity (3 V/m,26 MHz to 1 Ghz,100% Square wave Modulation)
- Steady State Voltage Fluctuations
- Line Voltage Dropouts
- Slow Line Voltage Sags and Surges
- Fast Transients Bursts per IEC 801-4
- Fast Line Voltage Surges
- Conducted Energy Immunity per MIL-STD-462D, Method CS114
- Magnetic Field Immunity per MIL-STD-482D,Method RS 101
- Quasi-Static Electric Field Immunity

None of the testing demonstrated any design characteristics that violated the requirements of the September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, FDA, Center for Devices and Radiological Health" or resulted in any safety hazards. It was the contract testing Laboratory's conclusions that the

device tested met all relevant requirements of the aforementioned guidance testing requirements.

8. **Discussion of Clinical Test Performed:**

Not Applicable

9. **Conclusions:**

The Perception Inc. GPS-RST Diagnostic Ultrasound System has the same intended use as a combination of all cited predicates. All non-clinical testing and biocompatibility testing revealed no new questions of safety or effectiveness. This, when compared to the predicate devices, the Perception Inc. GPS-RST Diagnostic Ultrasound System does not incorporated any significant changes in intended use, method of operations, material or design that could affect safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 1998

Susan D. Goldstein-Falk
Official Correspondent
Perception, Inc.
9344 N.W. 13th Street, Suite 200
Miami, FL 33178

Re: K974880
GPS-RST Diagnostic Ultrasound System
Dated: May 1, 1998
Received: May 4, 1998
Regulatory class: II
21 CFR 892.1550/Procode: 90 IYN
21 CFR 892.1560/Procode: 90 IYO

Dear Ms. Goldstein-Falk:

We have reviewed your section 510(k) 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 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. You may, therefore, market the device, subject to the general controls provisions Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Perception GPS-RST Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

GP - 3.0 MHz Mechanical Sector
LA - 7.5 MHz Linear Array
PV - 12.5 MHz Mechanical Sector

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

Please note: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for David A. Seymour

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Diagnostic Ultrasound Indications for Use Form

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

GPS-RST – ULTRASOUND SYSTEM

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

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

Additional Comments: NONE

Prescription Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K974880

Diagnostic Ultrasound Indications for Use Form

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

GP-3.0 MHz Mechanical Sector-Transducer

	Mode of Operations									
Clinical Application	**A**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Amplitude Doppler**	**Color Velocity Imaging**	**Combined (specify)**	**Other (specify)**
Ophthalmic										
Fetal										
Abdominal		X	X		X					
ntraoperative(specify										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonathal Cephalic										
Adult Cephalic										
Cardiac		X	X		X					
Transesophageal										
Transrectal										
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: NONE

David A. Legzdon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K974880

Prescription Use _____
(Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

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

LA-7.5 MHz Linear Array-Transducer

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

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

Additional Comments: NONE

David A. Seguson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

Prescription Use _____
(Per 21 CFR 801.109)

510(k) Number K974880

Diagnostic Ultrasound Indications for Use Form

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

PV-12.5 MHz Mechanical Sector-Transducer

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

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

Additional Comments: NONE

David A. Seyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

Prescription Use _____
(Per 21 CFR 801.109)

510(k) Number K974880