

DEC 17 1997

EXHIBIT #2

Page 1 of 4

510(K) SUMMARY

K972192

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:_____.

1. **Submitter's Identification:**

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

Date Summary Prepared: June 9, 1997

2. **Name of the Device:**

Perception Inc. GPS-XYZ Diagnostic Ultrasound System

3. **Predicate Device Information:**

- 1) Aloka Model SSD650CL Ultrasound Systems and Transducers, K# 925486/920374.
- 2) Bruel and Kjaer Diagnostic Ultrasound Type 3535 System and Transducers 8549, 8434, 8536, 8537, 8551 and 8550, K#905198/914925.
- 3) Sharplan, USight 9010, K#945796.
- 4) International Ultrasound Systems Inc., Model AU-530, Pre-amendment Device.

4. **Device Description:**

General Description

The GPS-XYZ Diagnostic Ultrasound System device is a diagnostic ultrasound system which produces two-dimensional diagnostic ultrasonic images. The following intended uses are identified for the transducer applications: General Radiology, Abdominal, Cardiac and Vascular, with the use of ultrasonic probes from 2.8-12.5 MHz. There are no transcranial applications for this device.

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

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

PROBE	CENTER FREQ	TYPE	INSP. MODES	APPLIC.
GP-3.0	2.8 MHz	MECH. SEC	M/B	Gen. Purpose/ Abdominal/ Cardiac
CA-3.5	3.7 MHz	CONV. ARR	B	Abdominal
PV-12.5	12.5 MHz	MECH SEC	M/B	Peripheral Vascular

5. **Intended Use:**

The GPS-XYZ device is a diagnostic ultrasound system which produces two-dimensional diagnostic ultrasonic images. The following intended uses are identified for the transducer applications: General Radiology, Abdominal, Cardiac and Vascular, with the use of ultrasonic probes from 2.8-12.5 MHz. There is no transcranial application for this device.

6. **Comparison to Predicate Devices:**

We believe the Perception Inc. GPS -XYZ 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 -XYZ Diagnostic Ultrasound System and predicate devices is attached to this summary.

7. **Discussion of Non-Clinical Tests 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 Intertec Testing Services:

- UL-544, Third Edition
- Radiated and Conducted Emissions per CISPR 11
- Magnetic Field Emission 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 RS101
- Quasi-Static Electric Field Immunity

None of the testing demonstrated any design characteristics that violated the requirements of the "FDA November 1993 Draft Reviewer Guidance for Pre-Market notification submissions, DCRND" or resulted in any safety hazards. It was Intertec Testing Services' conclusion that the device tested met all relevant requirements of the aforementioned guidance testing requirements.

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

Not Applicable

9. **Conclusions:**

The Perception Inc. GPS-XYZ 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-XYZ Diagnostic Ultrasound System does not incorporate any significant changes in intended use, method of operations, material or design that could affect safety or effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Perception Inc.
Susan Goldstein-Falk
C/O MDI Consultants Inc.
55 Northern Blvd. Suite 410
Great Neck, NY 11021

DEC 17 1997

Re: K972192
GPS-XYZ (Diagnostic Ultrasound System)
Dated: August 25, 1997
Received: September 23, 1997
Regulatory Class II
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 GPS-XYZ, as described in your premarket notification:

Transducer Model Number

3.0 MHz GP-3.0
3.5. MHz CA-3.5
12.5 MHz PV-12.5

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 regulation (CFR Part 820) and that, through periodic QS inspections, the Food and Drug

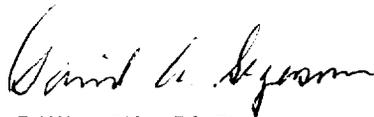
Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 "dsmo@fdadr.cdrh.fda.gov".

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

Sincerely yours,


for Lillian Yin, Ph.D.

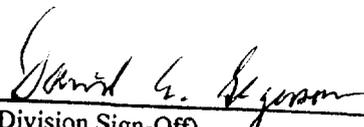
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

CLINICAL APPLICATIONS/OPERATING MODES

TABLE A.1

GP-3.0 General Purpose 3.0 MHz Mechanical Sector

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		x	x							
Intra-Operative (Specify)										
Intra-Operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		x	x							
Trans-Esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular										
Laparoscopic										
Musculo-Skeletal Conventional										
Musculo-Skeletal Superficial										
Other (Specify)										



 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K973192

Prescription Use _____
 (Per 21 CFR 801.109)

TABLE A.2

CA-3.5 Curved Array 3.5 MHz Electronic

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		x								
Intra-Operative (Specify)										
Intra-Operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-Esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular										
Laparoscopic										
Musculo-Skeletal Conventional										
Musculo-Skeletal Superficial										
Other (Specify)										

David A. Seymour
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K972192

Prescription Use
 (Per 21 CFR 801.109)

TABLE A.3

PV-12.5 Peripheral Vascular 12.5 MHZ Mechanical Sector

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative (Specify)										
Intra-Operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-Esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular		X	X							
Laparoscopic										
Musculo-Skeletal Conventional										
Musculo-Skeletal Superficial										
Other (Specify)										

David C. Seeger
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K972192

Prescription Use _____
 (Per 21 CFR 801.109)