FEB 12 2014

510(k) Summary
HyperSound Health Audio System Model HSS-3000 (HSS) – Group Auditory Trainer
510(k) Number: K133352

1. Submission Sponsor –

HyperSound Health, Inc.
13771 Danielson Street, Ste. L
Poway, California 92064
USA
Phone: 888-496-8001
Fax: 888-639-2150
Contact: Gus Bock, Management Representative

2. Date Prepared –

October 23, 2013

3. Device Name –

Trade/Proprietary Name:	HyperSound Audio System (HSS)
Common/Usual Name:	Group Auditory Trainer
Classification Name:	Group Auditory Trainer or Group Hearing Aid
Classification Regulation:	874.3320
Classification Panel:	Ear Nose and Throat
Product Code :	EPF
Device Class:	Class II
K Number:	K133352
FDA Establishment Registration #:	348096

4. Predicate Device –

(1) Phonic Ear, Inc. ***K043090***, SE: 12/23/2004

5. Device Description –

The HyperSound Audio System (HSS) utilizes a specially designed emitter (speaker) that delivers beam-like sound that is clear to the listener. The beamed audio content begins to demodulate in the air within six inches of the emitter and results in a cone-like transmission of sound waves that can be directed towards the listener. This device is intended for sale as an over-the-counter product and can be used with any sound source and at any distance from 3 feet to 50 feet or more from the emitters (speakers). Ultrasonic technology has been used for many years in industry and is also utilized in medical devices, such as ultrasonic nebulizers. The ultrasonic sound waves this product is based upon have also used in commercial and localized communication applications, and they are below the ultrasonic sound safety limits established by OSHA as required by OSHA Noise Standard, 29 CFR 1910.95.

The device consists of an amplifier, software, and an emitter (speaker). No ear plugs or head phones are required to use this device. The device is distant from and does not touch the intended patient/user.

6. Indications for Use –

The HyperSound Group Auditory Trainer is indicated for use as a group auditory trainer or group hearing aid used to communicate simultaneously with one or more listeners with or without hearing loss and with or without the use of hearing aids in order to improve clarity and comprehension of sounds generated from sources such as a microphone, CD/DVD player, TV, Stereo System or other sound generation systems.

7. Technological Characteristics and Substantial Equivalence –

The following table compares the HyperSound Audio System to the Predicate Devices with respect to intended use, technological characteristics and principles of operation. These comparisons provide more detailed information regarding the basis for the determination of substantial equivalence.

The HyperSound Audio System (HSS) shares the same basic technology as standard consumer amplifiers and speakers as well as those speakers used in certain group auditory trainers, group hearing aids and assistive listening devices. Similar and substantially equivalent to K043090 (Easy Listener 2 FM) and other sound field amplification systems, HSS employs reproducing audio in the air and not through any coupling to the ear through either earphones or ear molds. There is no contact with the body. HSS is also substantially equivalent to various types of approved Group Hearing Aids or Group Auditory Trainers that are directly connected or coupled to the listener with similar results.

Device Proprietary Name	**Submitted Device HyperSound Audio System**	**Easy Listener 2 FM**
510(k) Number	Being submitted	***K043090***
Device Classification Type and Classification Name	Class II Group hearing aid or auditory trainer	Class II Group hearing aid or auditory trainer
Manufacturer	HyperSound Health, Inc.	Phonic Ear, Inc.
Product Code	EPF	EPF
Regulation Number	874.3320	874.3320

Device Proprietary Name	Submitted Device HyperSound Audio System	Easy Listener 2 FM
Intended Use	The HyperSound Audio System is intended to be used to improve the clarity of sound in the home, business, school or other institutional environment by individuals or groups with or without hearing loss and with or without hearing aids. The device is intended to overcome any negative effects of distance, poor room acoustics and background noise to improve clarity (speech understanding and speech discrimination) for those with normal hearing or the hearing impaired with mild to severe hearing loss without earphones or ear- molds.	Sound Field wireless amplification systems are intended for use as group auditory trainers used to communicate simultaneously with one or more listeners with normal hearing or hearing impairments. The device is used with an associated transmitter microphone and speakers systems and does not provide coupling to the ear through either earphones or ear molds. The use of FM systems also reduces the detrimental effects caused by the distance between the speaker or sound source and the hearing impaired listener.
Indications for Use	The HyperSound Group Auditory Trainer is indicated for use as a group auditory trainer or group hearing aid used to communicate simultaneously with one or more listeners with or without hearing loss and with or without hearing aids in order to improve clarity and comprehension of sounds generated from sources such as a microphone, CD/DVD player, TV, Stereo System or other sound generation systems.	Sound Field wireless amplification systems are intended for use as group auditory trainers used to communicate simultaneously with one or more listeners with normal hearing or hearing impairments. The device is used with an associated transmitter microphone and speakers systems and does not provide coupling to the ear through either earphones or ear molds. These systems use FE and/or wireless technology which include receivers, transmitters, and strategic placement of high quality speaker systems and can be used with or without BTE hearing aids nad/or personal FM devices. The talker's voice is mildly amplified and dispersed throughout the room to assist listeners, regardless of seating location, to consistently hear whatever the talker is saying.
Overall Design	A microphone, CD/DVD or other sound source is routed to an amplifier, which mixes audible sound with an ultrasonic carrier. The output is sent to specially designed emitters (speakers), which deliver the waves to produce sound into the air through a conical beam. The waves begin to demodulate into high quality sound waves within six inches of the emitter and continue to travel within a conical beam to the desired area. The sound is clearly delivered to the listener at normal volume levels free with reduced external noise. The HSS System may be portable or installed permanently by a sound contractor.	The device consists of FM or IR transmitters and microphone used by a speaker to send auditory signals to FM or IR receiver/amplifier which processes the voice signals and broadcasts the signals through one or more loudspeakers. These systems may be installed by a sound contractor. Sound is reproduced by the speaker or speaker systems to recreate the sound at a slightly increased volume level.

Device Proprietary Name	Submitted Device HyperSound Audio System	Easy Listener 2 FM
How it Works	HSS electronically mixes audible sound with an ultrasonic carrier. These audible tones are projected within a beam of silent energy heard by those in the targeted area. Unlike a conventional speaker, sound is not created omni-directionally at the emitter (speaker) surface but is created along and within a highly directional air column. Sound is only heard if a listener's head is within the beam or the beam hits a reflective surface whereupon sound is created at the point of reflection. This sound, which is created in the air, can be directed to nearly any desired point in the listening environment, controlling the direction of sound.	The system works essentially as a monaural or stereo system for the processing of sound input through the amplifier for delivery to the speakers placed throughout the audience. Sound is not directional and outside noise may comingle with the sound delivered. FM or IR are used in lieu of cables, but serve the same purpose.
Physical dimensions	Amplifier 6x6x1.5 inches, individual or multiple emitters: 12.5x6.5x1 inches	Varies based on type of FM transmitter, receiver and speaker(s) employed
Maximum audio output characteristics	89dB SPL @ 1m	90dB SPL @ 1m
Frequency range	Generally 300Hz to 18kHz (may be used with off-shelf consumer powered woofer where improved bass (lower frequencies) is desired)	Generally 50Hz to 20kHz depending on speaker size type
Energy used	< 15 watts per channel	Generally 30W per speaker
Transducer type	Custom emitter (speaker)	Conventional speaker
Safety	HyperSound delivers audio through the air within a conical beam and without any earphone or ear mold to deliver sound free of external sounds or sources of distortion. Users are instructed to not aim an emitter (speaker) directly in to the ear canal of an individual at less than 3 feet distance. The amplifier is CE compliant, FCC compliant (Part 15, Subpart B) and approved for Electrical Safety by Nemko CCL (Nationally Recognized Testing Laboratory).	There are no known contraindications associated with the use of sound field group amplification systems. Many case studies, experiments, and trials exist that document the benefits and effectiveness of speech perception from sound field amplification. Amplifier and speakers meet FCC and Consumer Electrical Safety requirements.

8. Non-Clinical Testing

Comparable systems using the same technology as the HyperSound Audio System have been in commercial use since 2001 for general audio use primarily commercial advertising systems. The manufacturer has submitted the applicable report to the FDA pursuant to the Radiation Control for Health and Safety Act of 1968 (Title 21, CFR, sub-chapter J) as it pertains to ultrasonic devices. Laboratory bench testing, comparative testing and verifications related to device performance, production of sound volume over distance, has demonstrated the HyperSound Audio System consistently and safely delivers clear and understandable sounds, letters and words to the patient or to the listener at distances from 3 feet to 50 feet or more with sound levels of up to 76.5 dB in normal listening and sound reproduction environments.

Both sound pressure level measurement and sound beam plotting measurements were performed to demonstrate equivalent output at various distances. Beam plotting demonstrated focused delivery of frequencies important to speech discrimination in a targeted beam important to augment hearing for selected users in home, classroom or other group settings without the need for headphones or segregation.

Equivalency testing to a predicate device was performed by an independent laboratory pursuant to ANSI S3.2-2009-American National Standard Method for Measuring the Intelligibility of Speech over Communication Systems. Testing of the HSS system demonstrated a mean ANSI S3.2-2099 MRT (Modified Rhyme Test) score of 91% and the predicate device had a mean score of 79.2% demonstrating more than equivalency in word list discrimination amongst normal subjects.

9. Clinical Testing –

A clinical study was conducted by the California Hearing and Balance Center in La Jolla, CA under a formal, written, Institutional Review Board (IRB) approved protocol. The clinical study was performed in a controlled audiology laboratory as a single-blinded, randomized cross over clinical study using adult subjects with hearing loss ranging from mild to severe degree. Testing was based upon speech tests (such as Modified Rhyme Test (MRT) and Consonant-Nucleus-Consonant or CNC in quiet and AzBio in noise) to assess the effectiveness of the HSS System compared to conventional speakers at comparable volume levels.

Ten adult patients with mild to severe hearing loss with pure-tone average (PTA) of > 30 dB and word discrimination scores of < 80% in both ears were tested at one meter distance from the audio source. Significant gains in speech understanding were associated with the HSS versus conventional speaker for all test conditions at 70 dB. Median AZBio scores increased from 0.0% to 34.9% ($p=0.008$) in quiet, and from 1.8% to 51.6% in noise ($p=0.008$). Median CNC whole word test scores increased from 0.0% to 54.0% ($p=0.004$) and median phoneme test scores from 4.0% to 63.4% ($p=0.004$).

Data and results demonstrated improvement in sound clarity over conventional speakers at 70 dB, including in background noise, in those with mild to severe hearing loss.

10. Conclusion –

By definition, a subject device (new device) is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device or the subject device has the same intended use and different technological characteristics that subject device can be demonstrated to be substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

The HyperSound Audio System meets these criteria, and as designed and manufactured, is considered to be substantially equivalent to the referenced predicate devices based on testing and clinical evaluation.

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

February 12, 2014

HyperSound Health, Inc.
c/o Mr. James Barnes
13771 Danielson Street, Ste. L
Poway, CA 92064

Re: K133352
Trade/Device Name: HyperSound Audio System (HSS)
Regulation Number: 21 CFR 874.3320
Regulation Name: Group Auditory Trainer or Group Hearing Aid
Regulatory Class: Class II
Product Code: EPF
Dated: January 15, 2014
Received: January 16, 2014

Dear Mr. Barnes:

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 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/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

HyperSound Health Audio System Model HSS-3000 (HSS) – Group Auditory Trainer

510(k) Number: K133352

Device Name: HyperSound Health Audio System Model HSS-3000 (HSS) – Group Auditory Trainer

Indications for Use:

The HyperSound Group Auditory Trainer is indicated for use as a group auditory trainer or group hearing aid used to communicate simultaneously with one or more listeners with or without hearing loss and with or without the use of hearing aids in order to improve clarity and comprehension of sounds generated from sources such as a microphone, CD/DVD player, TV, Stereo System or other sound generation systems.

Prescription Use _____ (Part 21 CFR 801 Subpart D)
AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Cherish R. Giusto -A