K091682

510 (k) Summary

21 CFR 807.92 (a) 1

AUG 20 2009

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The Trade name of the device is **LSVT Companion**; the name LSVT is registered trademark by the U.S. Office of Patents.

The Device Classification Name is **AIDS, SPEECH TRAINING FOR THE HEARING IMPAIRED** as shown in 510 (k) number K982396 for the VISIVOX for which we claim equivalence.

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IDENTIFICATION OF THE LEGALLY MARKETED DEVICE TO WHICH LSVT GLOBAL LLC IS CLAIMING EQUIVALENCE

The legally marketed device to which LSVT Global, LLC is claiming equivalence is the

RSQ, LLC Visivox, Model V-2

which was approved for marketing on September 14, 1998 under 510(k) K982396

RSQ, LLC is the assignee of the following patent:

Patent number: 5774558
Filing date: Oct 24, 1996
Issue date: Jun 30, 1998
Inventor: Doris Drucker
Assignees: RSQ, LLC

U.S. Classification
381/56; 340/573; 381/58

International Classification
H04R 2900

Device Classification Name: AIDS, SPEECH TRAINING FOR THE HEARING IMPAIRED (AC POWERED AND PATIENT CONTACT)

Applicant: LSVT Global, LLC

Product Code: LEZ

Classification Advisory Committee: EAR, NOSE & THROAT

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DESCRIPTION OF THE DEVICE

The sound produced by an individual's voice is received by a calibrated microphone and converted to a visual display which consists of different visual and auditory feedback. The individual is given a target range of both vocal intensity (loudness) and fundamental frequency (pitch) and instructed to maintain a given loudness and or pitch for a given duration. Increases in the complexity of the spoken material are combined with these targeted vocal parameters. In this way, individuals are trained to increase both vocal loudness and variations in pitch through a series of exercises. This approach is designed for speech and hearing impaired adults, over the age of 18, who are unable to speak at a consistent and audible level of loudness such as those with Parkinson's disease and other causes.

The device consists of software that allows clinicians to manage speech therapy for clients as well as allow clients to perform speech "homework" on their home PC The Graphical User Interface (GUI) contains two modes of operation – client and clinician. In each mode, the speech therapy tasks are presented to the user and feedback is continually being given. The device collects data on the variables trained (vocal sound pressure level, fundamental frequency, and duration of phonation) and directs individuals through a series of speech exercises, while providing online feedback.

These data are recorded to a file that can be downloaded and analyzed by the clinician. Targets for vocal loudness, F0 and duration can be individualized and revised

as often as needed. The interface was developed to be simple to use, while carefully considering the specific visual, motor, cognitive and voice/speech needs of individuals with Parkinson's disease and other communicative impairments. The backgrounds were designed in bright contrasting colors which have common meaning (e.g., green means "go") to make the targeted goals easier to identify. In addition, the visual displays utilize concrete, familiar objects (e.g., thermometer, piano, clock) which are designed to be intuitive and require little interpretation. Due to the fact that the device is intended to be used without a face to face clinician, feedback emulates what would be received from a clinician in a therapy session. Thus, in addition to the written comments shown on the screen, a wide variety of auditory feedback phrases, such as "Good job!", "Let's get louder," "Great!", "Can you go any higher?", and short instructions at the beginning of each exercise have been incorporated.

The Sound Server works with the GUI in that it sends it data from the microphone at regular intervals so that graphs can be created, feedback can be given to the user, and results for the speech tasks can be written.

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SUMMARY OF THE NEW DEVICE COMPARED TO THE PREDICATE DEVICE

Intended Use [21 CFR 807.92 (a) 5]

The intended use of the predicate device is as follows: "To be used as an assistive device and training aid, complementing person-to-person speech therapy:

1. For the deaf, and for people with hearing impairments who do not perceive the loudness of their speech.
2. For people with speech impairments who are unable to speak at a consistent and audible level of loudness. The impairments may be due to stroke, Parkinson's, traumatic head or spine injuries, cleft palate, laryngectomies or other causes.
3. For speech-and/or hearing impaired people of any age who are able to follow the directions of a speech therapist or audiologist"

The intended use of the new device the LSVT Companion is as follows:

To be used as a technical aid complementing person-to-person speech therapy to improve the vocal loudness of persons with Parkinson's disease.

To be used with adults, 18 years of age and older, with speech/voice impairments that result in inadequate vocal loudness or control of loudness due to other neurological disorders or injury including stroke, traumatic brain injury, multiple sclerosis, ataxia, vocal fold paralysis or other causes.

To be used for voice/speech impaired adults, 18 years of age or older, who are able to follow the directions of a Speech-Language Pathologist.

This device is sold only to licensed practitioners who have also completed a 2 day certification workshop on the LSVT (Lee Silverman Voice Treatment) behavioral therapy protocol. This certifies them to provide LSVT for patients with Parkinson's disease and other communicative impairments.

The following specific labeling, therefore, is provided on the product:

Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.

Technological Characteristics [21 CFR 807.92 (a) 6]

The New Device has similar technological characteristics as the predicate with the modernization that the device uses hardware and software as opposed to just hardware in the predicate device to transduce and provide feedback for vocal loudness.

In the new device, a calibrated microphone is used with a PC based software program to receive a speaker's acoustic signals. Targeted visual and auditory feedback is provided through a series of speech tasks. In the legally marketed device a microphone is attached to a hardware device imbedded in a box. Acoustic signals are converted to LED displays is logarithmic 3 db steps that vary with the individual's vocal loudness. The overall goal is to enable individual's to maintain vocal loudness at appropriate levels through this targeted visual feedback. This is extremely similar to the new device which adds auditory feedback to visual feedback and enables targeted vocal ranges to be established to improve both vocal loudness and fundamental frequency. The hardware device in the legally marketed device is substituted by a graphical user interface and other software components as described above. These differences are not critical to the intended therapeutic use of the device.

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807.92 (b) (1, 2, 3)

ASSESSMENT OF NON-CLINICAL AND CLINICAL PERFORMANCE DATA

The only assessment known to the applicant that refers to the predicate legally marketed device is that provided in their previous 510(k) summary document and refers to the opinions of two practicing speech language pathologists of the utility of using the visual feedback instrument to improve vocal loudness in speech disordered and other individuals.

The new device in PDA form was the subject of a preliminary clinical investigation designed to explore device efficacy and user satisfaction. Sixteen individuals with PD were able to independently use the new device and showed therapeutic gains similar to those following classically/traditionally administered speech therapy. *These gains were significant from pre to post and pre to follow-up and absolutely no adverse effects of using the assistive technology to improve vocal loudness.* Individuals were highly enthusiastic about the use of the assistive technology. References to published abstracts referring to the new device are provided below. Anecdotal reports of the speech language pathologists participating in the study reveal that they were highly encouraged by the results and thus reported similar satisfaction as those referenced in the predicate device. We suggest, therefore, that performance data are highly similar between the New Device and the predicate.

References

Halpern, A., Matos, C., Ramig, L., Petska, J., Spielman, J., & Will, L. (2005). Technology supported speech treatment for Parkinson's disease. Movement Disorders, 20(10), p. S134.

Halpern, A., Matos, C., Ramig, L., Petska, J., Spielman, J., Bennett, J. LSVTC- A PDA Supported Speech Treatment for Parkinson's Disease. Presented at the Coleman Institute for Cognitive Disabilities, "Research Frontiers & Partnerships in Cognitive Disability and Technology" Conference, October 9-10, 2003, Aurora, Colorado.

Halpern, A., Matos, C., Ramig, L., Petska, J., Spielman, J., Bennett, J. LSVTC- A PDA Supported Speech Treatment for Parkinson's Disease. Presented at the Twelth Biennial Conference on Motor Speech, March 18-21, 2004, Albuquerque, New Mexico.

Halpern, A., Matos, C., Ramig, L., Petska, J., Spielman, J., Bennett, J., Will, L. LSVTC- A PDA Supported Speech Treatment for Parkinson's Disease. Presented at the International Association of Logopedics and Phoniatrics, Brisbane, Australia, 2004.

Halpern, A., Matos, C., Ramig, L., Petska, J., Spielman, J., Cole, R., Yan, J., Will, L. Technology Supported Speech Treatment for Parkinson's Disease. Poster presented at the 9th International Congress of Parkinson disease and Movement disorders, March 5-8, 2005, New Orleans, Louisiana.

Halpern, A., Matos, C., Ramig, L., Petska, J., Spielman, J., Will, L. LSVTC- A PDA Supported Speech Treatment for Parkinson's Disease. Presented at the Annual Conference of the American Speech-Language Hearing Association, Philadelphia, Pennsylvania, 2004.

Halpern, A., Matos, C., Ramig, L., Spielman, J., Bennett, J. PDA-Enhanced Speech Treatment for Parkinson's Disease, Presented at the Fifth Annual Meeting of the American Society for Experimental NeuroTherapeutics, Washington DC, March 13-15, 2003.

Halpern, A., Matos, C., Ramig, L., Spielman, J., Bennett, J. PDA-Enhanced Speech Treatment for Parkinson's Disease. Presented at the Eleventh Biennial Conference on Motor Speech, March 14-17, 2002, Williamsburg, Virginia.

Matos, C., Halpern, A., Ramig, L., Spielman, J., Bennett, J. Updates to PDA-Enhanced Speech Treatment for Parkinson's Disease. Presented at the Coleman Institute for Cognitive Disabilities, "Research Frontiers & Partnerships in Cognitive Disability and Technology" Conference, September 26-27, 2002, Boulder, Colorado.

Substantial Equivalence Table (see also Substantial Equivalence Flow Chart as Attachment II)

Characteristic	Predicate	LSVT C or LSVT Companion
Intended Use:	"To be used as an assistive device and training aid, complementing person-to-person speech therapy: 1. For the deaf, and for people with hearing impairments who do not perceive the loudness of their speech. 2. For people with speech impairments who are unable to speak at a consistent and audible level of loudness. The impairments may be due to stroke, Parkinson's, traumatic head or spine injuries, cleft palate, laryngectomies or other causes. 3. for speech-and/or hearing impaired people of any age who are able to follow the directions of a speech therapist or audiologist"	The LSVT Companion Device is designed: To be used as a technical aid complementing person-to-person speech therapy to improve the vocal loudness of persons with Parkinson's disease. To be used with adults, 18 years of age and older, with speech/voice impairments that result in inadequate vocal loudness or control of loudness due to other neurological disorders or injury including stroke, traumatic brain injury, multiple sclerosis, ataxia, vocal fold paralysis or other causes. To be used for voice/speech impaired adults, 18 years of age or older, who are able to follow the directions of a Speech-Language Pathologist.
Target Population	Persons of any age	Adults, 18 years of age and older
Physical Characteristics:	A microphone is attached to a hardware device imbedded in a box. Acoustic signals are converted to LED displays in logarithmic 3 db steps that vary with the	A calibrated microphone is used with a PC based software program to receive a speaker's acoustic signals. Targeted visual and auditory feedback is provided through a series of

	individual's vocal loudness. The overall goal is to enable individual's to maintain vocal loudness at appropriate levels through this targeted visual feedback.	speech tasks. The hardware device in the legally marketed device is substituted by a computer, a graphical user interface and other software components.
Where Used	Inside and outside of a clinical setting	Inside and outside of a clinical setting
Performance Data:	Two practicing speech language pathologists report the utility of using the visual feedback instrument to improve vocal loudness in speech disordered and other individuals.	The LSVT Companion in PDA form was the subject of a preliminary investigation to explore device efficacy and user satisfaction. Sixteen individuals with PD were able to independently use the LSVT Companion and showed therapeutic gains similar to those following classically/traditionally administered LSVT therapy. These gains were significant from pre to post and pre to follow-up *and there were absolutely no adverse effects of using the assistive technology to improve vocal loudness.* Individuals were highly enthusiastic about the use of the assistive technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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Silver Spring, MD 20993-0002

LSVT Global, LLC
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Tucson, AZ 85750

AUG 20 2009

Re: K091682
Trade/Device Name: LSVT C or LSVT COMPANION, MODE
Regulation Number: Unclassified
Regulation Name:
Regulatory Class: Unclassified
Product Code: LEZ
Dated: 5/26/2009
Received: 6/10/2009

Dear Mr. McFarland:

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Indications for Use

510(k) Number (if known): K091682

Device Name: LSVT C or LSVT Companion

Indications for Use

The LSVT Companion Device is designed:

To be used as a technical aid complementing person-to-person speech therapy to improve the vocal loudness of persons with Parkinson's disease.

To be used with adults, 18 years of age or older, with speech/voice impairments that result in inadequate vocal loudness or control of loudness due to other neurological disorders or injury including stroke, traumatic brain injury, multiple sclerosis, ataxia, vocal fold paralysis or other causes.

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The LSVT Companion is designed as a technical aid for this behavioral intervention to increase communicative effectiveness. A "home study" function allows patients to complete voice exercises either under direct supervision by the practitioner in the clinic environment or at home, with feedback of performance provided to the clinician by results reporting via e-mail.

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

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K091682