K982396

RSQ, LLC.
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Claremont, CA 91711

Tel(909)626-3172;Fax(909)626-7366
Email:RSQ@earthlink.net
Web:http://www.visivox.com

510(k) SUMMARY
[807.92(a)(1)]

Submitter's Name	Doris Drucker
Submitter's Address	636 Wellesley Drive Claremont,CA 91711-3427
Submitter's Telephone Number	(909) 626-3172
Submitter's Fax Number	(909) 626-7366
Contact Person:	Submitter
Date of Preparation of Summary	June 30,1998

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510(k) SUMMARY.
[807.92(A)(2)]

The Proprietary name of the device is **VISIVOX**; the name is registered as a trademark by the U.S.Office of Patents.

The Trade name is also **VISIVOX.**

The Common Name is **Voice Level Monitor**

The Device Classification Name is **Aids,Speech Training for the Hearing Impaired** as shown in 510(k) Number K802870, for the Rion Electro-Palatograph to which we claim equivalence.

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510(K) SUMMARY

IDENTIFICATION OF THE LEGALLY MARKETED DEVICE TO WHICH RSQ,LLC. IS CLAIMING EQUIVALENCE.
[807.92(a)(3)]

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

RION ELECTRO-PALATOGRAPH, Model DP-01

which was approved for marketing on December 17,1980 under 510(k) K802870.

RION Co.,Ltd. Tokyo,Japan, is the assignee of the following two patents:

U.S.Patent No.4287895 ELECTRO-PALATOGRAPH, issued on 9/8/1981 to HORI, KIYOHARU, Hino,Japan,

and

U.S.Patent No.4310002 ELECTRO-PALATOGRAPH, issued on 1/12/1982 to TAKINISHI;KIYOTOSHI,Koganei,and IWASAKI;SHINGI,Tachikawa,Japan

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

Applicant: KINDEL & ANDERSON

Product Code: LEZ

Classification Advisory Committee: EAR,NOSE & THROAT.

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510(k) Summary
[807.92(a)(4)

DESCRIPTION OF THE DEVICE

The sound volume produced by an individual's voice is received by a microphone and converted into a visual display which consists of a series of multicolored light-emitting diodes arrayed on a light-bar. The number and color of the lights which are sequentially actuated represent changes in the sound volume. Each of the sixteen lights represents a logarithmic 3dB per step variation in the volume of the acoustic signals.

The device consists of a metal box, dimensioned 11.75"x 8.25" x 2.75" which weighs 9.5 lb. A hinged lid allows access to the interior. A 12V lead-acid battery and the electronics required for operation of the device are affixed to the interior of the box. A transformer/recharger, a first cable having an external microphone at one end, and a second cable having a light-bar comprising a plurality of light-emitting diodes at one end, are stored, unanchored, inside the box. The front panel of the box includes an off/on switch, a volume adjustment knob, a battery recharger connector, a light-bar connector, an internal microphone, an external microphone connector, and a battery status indicator light.

A perspective view of the box is shown in the Proposed Users Guide (Exhibit #2)

A schematic diagram of the electronics is shown in Exhibit #5.

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Power is supplied by the 12V battery and/or, via the battery recharger, by 120V AC current.

To operate the device, the free end of the cable having the light bar at its other end, is plugged into the designated connector at the outside of the box; the speaker is positioned so as to face the built-in microphone, and the light bar is placed within his or her line of vision. The volume is adjusted so that no light signals are displayed. Upon receiving acoustic signals from a speaker one or more lights will appear- and disappear - depending on the sound volume produced by a speaker. If it is inconvenient for a speaker to face the built-in microphone, (for instance, if he or she is bedridden or in a wheelchair) the cable with the external microphone at its free end may be plugged in. The external microphone may then be handheld or deposited in a clasp provided on the light bar, so that it faces the speaker. Substitution of the external microphone shuts off the built in microphone to prevent interference.

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510(k) SUMMARY
[807.92(a)(6)

SUMMARY OF TH TECHNOLOGICAL CHARACTERISTICS OF THE NEW DEVICE COMPARED TO THE PREDICATE DEVICE

In the **new** device a microphone is embedded in a box so as to receive a speaker's acoustic signals over the air. There is no contact between a speaker and the device. A transducer, connected to the microphone, converts the acoustic signals into electric signals which are amplified and transmitted to light-emitting diodes (LEDS). Upon receiving the signals the LEDS emit radiation in the optically visible range. The LEDS are arrayed in a series which represents a logarithmic 3 dB per step variation in the volume of the acoustic signals.The output is a spectrographic image in which lights of specific wavelengths represent the intensity of the received sound.The lights ranging from green to near infra-red provide visual feedback of the patient's voice volume. The display is emitted within a fraction from the time it is received and continuously holds until the new information arrives.

In the **legally marketed** device speech output is also transformed into electric signals which trigger a visual feedback. The approach differs in that the transformation occurs inside the patient's body by contact with specific speech organs. Specifically, tongue-contact signals representing linguapalatal contact modes are detected through sensing electrodes mounted on an artificial palate

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which is inserted into a patient's mouth. A signal voltage applied to the electrodes waves is also disposed within the trainee's mouth. Means are provided to transmit the electric waves to a receiver disposed outside the patient's body where they are perceived as visual signals.

(See *"Role of Visual Feedback treatment for defective /s/ sounds in patients with cleft palate"* by Michi K.et al. in J.Speech Hear Res 1993 Apr:36 (2); 277-85 where the authors mention that "visual feedback for tongue placement was provided by the Rion Electropalatograph".)

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510(k) SUMMARY.

ASSESSMENT OF NON-CLINICAL PERFORMANCE DATA,
[807.92(b)(1)]

The only assessment known to applicant which refers to the **legally marketed device** is described in the above-mentioned article in the Journal for Hearing Research which states that "visual feedback for tongue placement.... was specially useful in the treatment of defective sounds".

One assessment referring to the **new device** for which equivalence is claimed, declares that" it is an excellent instrument for complementing person-to--person therapy." (Tracy Lloyd, Speech Therapist, Long Beach Memorial Medical Center, Long Beach,CA.

Another assessment says : "Sometimes patients speak so low that they are not able to be understood well. This device is very useful because the speech therapist doesn't always have to interrupt them and tell them to speak louder". (Jill Wilkerson, director of Speech & Hearing, Casa Colina Centers for Rehabilitation, Pomona,CA.

The two assessments confirm the importance of visual feedback and support our claim that the effectiveness of the new device and of the legally marketed device is the same.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 1998

Doris Drucker
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Claremont, CA 91711

Re: K982396
Visivox, Model V-2
Dated: June 30, 1998
Received: July 9, 1998
Regulatory class: Unclassified
Procode: 77 LEZ

Dear Mr. Drucker:

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 (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.

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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 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 510(k) 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 the 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) 594-4613. 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 (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

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

510(k) Number (if known): K982396

Device Name: VISIVOX MODEL V-2

Indications For 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, Parkinsons', 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyttle

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982396

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)