DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 4 2005

Vivosonic, Inc.
c/o Entela, Inc.
Mr. N. E. Devine, Jr.
3033 Madison Ave. SE
Grand Rapids, MI 49548

Re: K043396
Trade/Device Name: Integrity, Model V500
Regulation Number: 21 CFR 882.1900
Regulation Name: Biomicroscopes
Regulatory Class: Class II
Product Code: GWJ; EWO
Dated: January 13, 2005
Received: January 14, 2005

Dear Mr. Devine:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, 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

510(k) Number (if known): K043396

Device Name: **INTEGRITY V500**

Indications for Use:

DPOAE and TEOAE Test Option
The Integrity V500 with DPOAE and TEOAE test options is indicated for use when it is necessary for a trained health care professional (for example, an Audiologist) to measure or determine cochlear function by measuring, recording, and displaying otoacoustic emissions. This device does not measure hearing, but helps to determine whether or not a hearing loss may be present, requiring further evaluation.

DPOAE and TEOAE tests do not measure hearing per se, but measure whether or not the cochlear hair cells are functioning. This device does not determine hearing levels, but allows the operator to establish specific pass or refer criteria.

ABR/ASSR Test Option
The Integrity V500 with ABR/ASSR options is indicated for auditory evoked potential testing as an aid in detecting hearing loss and lesions in the auditory pathway.

The Integrity V500 is a prescription device. The labeling, instructions and user operations are designed for trained professionals.

Prescription Use: Yes (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use: No (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

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

510(k) Number K043396