K964432

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SECTION 2: SUMMARY AND CERTIFICATION

510(K) SUMMARY

SAFETY AND EFFECTIVENESS SUMMARY

Safety and effectiveness information concerning this modification to the Scout OAE device is summarized below.

Because this is not a CLASS III device, the special certification defined for this section is not required.

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DATE ON WHICH THE SUMMARY WAS PREPARED:	October 7, 1996
NAME OF DEVICE:	Modification and Software Feature Addition to the Scout Otoacoustic Emissions (OAE) Test Instrument.
COMMON NAME:	Otoacoustic Emissions Test Instrument
CLASSIFICATION NAME:	Audiometer (per CFR 874.1050).
PREDICATE DEVICE:	Bio-logic Scout OAE Instrument (K944735)

REVISED STATEMENT OF INTENDED USE FOR 510(k) #K964132

INTENDED USE: The intended use of the current Scout Otoacoustic Emissions Test Instrument is to measure or determine cochlear function either by measuring and recording transient (click evoked) otoacoustic emissions or by measuring and recording distortion product otoacoustic emissions utilizing continuous pure tones. The intended use of this new software feature is essentially the same as that of the predicate device. It provides for an additional test methodology which measures DPOAE threshold instead of the more-routine DPOAE amplitude test. The threshold test (also called the Input/Output (I/O) function) involves varying the stimulus intensity levels while keeping the frequencies constant. Both test methods can be effectively used to differentiate normal and hearing- impaired subjects, but the amplitude test is usually preferred because it usually requires a shorter testing time. However, in cases where the amplitude test results in a DP-gram with a low DP response (close to the noise floor) at specific frequencies, the I/O function test can be used to determine if there is an improved response at other stimulus frequencies. Therefore, the I/O function test offers the potential to improve the identification of patients with normal hearing.

DPOAE threshold is the lowest stimulus intensity level which produces a DPOAE response amplitude that is distinguishable from the level of system distortion and from the noise floor. DPOAE threshold is expressed in much of the published literature as the lowest intensity of the F2 stimulus that generates a clear DPOAE response. DPOAE threshold does not equate to and should not be confused with audiometric or auditory threshold. Whereas auditory threshold measures assess the integrity of the entire auditory system from outer ear to cortex, DPOAE threshold measures are limited to assessment of outer hair cell function in the cochlea only.

(This statement replaces the text on pages 8 and 11 of the original 510(k) submission.)

PATIENT POPULATION: Adults, children and infants.

SAFETY AND EFFECTIVENESS:

No changes have been made to the hardware design of the Scout product line. Therefore, the Scout product which incorporates this new software feature does not present any safety issues which have not already been addressed in the predicate Scout 510(k) notifications. Also, the Scout software modules which are used to control the hardware have not been changed. This new feature only changes the sequence in which tones of varying intensity and frequency are generated when conducting a test. Instead of keeping stimulus intensity constant and varying frequency, the frequencies are kept constant and the stimulus intensity is varied. Therefore, this new feature does not affect the safety of the Scout product.

To establish the safety and effectiveness of the software which controls the Scout OAE Test Instrument with the addition of the Input/Output feature, the system was validated in accordance with the IEEE Standards for Software Engineering, as well as Bio-logic internal software development policies and procedures modeled after the IEEE Standards. Changes to the standard Scout PC computer program necessary to generate new test sequences and the presentation of this data were all developed and tested as specified in these procedures. The system, for which this application is submitted, was verified and validated; it was found to perform in accordance with specifications.

The following comparison is provided as a summary of technological characteristics relative to the predicate device Scout. This is to demonstrate that the addition of this new Input/Output software feature creates no significant differences which would adversely affect product safety and effectiveness.

Parameter for comparison.	Similarity or Difference.
Intended Use	No differences.
Population	No differences.
Hardware Configuration	No differences.
Computer Control Software	Only differences are changes to Scout software required to support the new Input/Output feature addition. There are no differences in software test algorithms.
Ear Probe System	No differences. The system still uses the Etymotic ER-10C probe.
Performance	The time to perform a DPOAE I/O (threshold) test is somewhat longer than that required for the more routine DPOAE amplitude test. However, the I/O test can provide additional information which the routine test cannot easily provide, which can, in some cases, be clinically useful.
Safety Characteristics	No difference. There is no direct electrical connection to the patient in any Bio-logic OAE system.