SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. General Information

A. Device Generic Name:	Implantable Middle Ear Hearing Device
B. Device Trade Name:	SOUNDTEC® Direct System℠ consisting of: Direct System Implant Assembly Direct System Earmold Coil Assembly Direct System Behind-the-Ear Sound Processor Assembly Surgeon's Set Clinician's Set User's Set Search Coil Set Test Coupler Set
C. Applicant's Name And Address:	SOUNDTEC, Inc. 2601 Northwest Expressway Suite 400 West Oklahoma City, OK 73112
D. Premarket Approval (PMA) Application Number	P010023
E. Date of Notice of Approval to the Applicant	September 7, 2001

II. Indications for Use

The SOUNDTEC® Direct System is indicated for use in adults, 18 years of age or older, who have a moderate to severe sensorineural hearing loss and desire an alternative to an acoustic hearing aid. Prior to receiving the device, it is recommended that an individual have experience with appropriately fit hearing aids.

III. Contraindications

The SOUNDTEC® Direct System is contraindicated for subjects who have conductive hearing loss, retrocochlear or central auditory disorder, active middle ear infections, tympanic membrane perforations associated with recurrent middle ear infections, and disabling tinnitus.

IV. Warnings and Precautions

The warnings and precautions can be found in the SOUNDTEC® Direct System labeling (attached).

V. Device Description

The SOUNDTEC® Direct System is a partially implantable, middle ear hearing device that works on the basic principle of energy transformation. Vibrational sound energy, induced by sound pressure, can be transformed into electromagnetic energy and conveyed to the middle ear's ossicles in this form. Specifically, electromagnetic energy vibrates the ossicles of the middle ear that have been coupled with a magnetic implant, leading to the perception of sound for the hearing impaired user.

The following is a summary of SOUNDTEC® Direct System operation. Acoustic sound vibrations are received by the microphone of an over-the-ear Sound Processor. The Sound Processor transforms this acoustic energy into electrical signals, which are amplified and transmitted to the Earmold/Coil Assembly in the ear canal. The alternating electromagnetic field of the Earmold/Coil Assembly results in attractive and repulsive forces on the magnet implant. The magnet implant is coupled with the middle ear ossicles, directly driving the ossicles' movement, producing amplified sound perception.

Device Components

The SOUNDTEC® Direct System consists of three main components: the implant, the Earmold/Coil Assembly (or ECA) and the Sound Processor (external amplification system)

1. Implant*:* The permanent magnetic implant directly drives the ossicles as it receives electromagnetic energy from the ECA (detailed below). The Neodymium-Iron-Boron ($Nd_2Fe_{14}B$) rare earth magnetic implant is attached via a wireform ring to the middle ear ossicles at the incudo-stapedial (IS) joint. The magnet is hermetically sealed in a 99.3% pure unalloyed titanium canister that meets the ASTM F67-95 Grade 2 specification for surgical implants. The attachment ring is composed of titanium alloy wire, which meets the ASTM F136-96 specification for surgical implants.

2. Earmold/Coil Assembly (ECA*):* The Earmold/Coil Assembly, or ECA, fits in the user's ear canal. The ECA transduces electrical signals electromagnetic energy from the Sound Processor (detailed below) and creates an alternating electromagnetic field with the magnetic implant. This electromagnetic field results in attractive and repulsive forces on the magnetic implant, driving the ossicles that are attached to it via the wireform ring.

The ECA consists of two components:

a. Electromagnetic coil:
The coil is composed of core material (HyMμ "80," Carpenter/Mμ encased by #43 copper bondable wire that has been coated with polyurethane. The core diameter and length are 1mm and 9.5 mm respectively; the total coil diameter and length are 2.24mm and 8mm respectively. The resistance of the electromagnetic coil is 40Ωand the inductance is 5.9 mH.

b. Earmold/Coil Assembly Casing*:*
The electromagnetic coil is embedded in plasticized Poly Methyl Methacrylate, a standard acrylic polymer used in hearing aids worldwide. This acrylic casing is obtained from the manufacturer in a clear form, which is indicated for medical use. The dimensions of the ECA casing are dependent on the size and shape of the user's ear canal, determined by a deep ear mold impression of the user's external ear and ear canal. Once the impression is taken, the ECA casing is molded to match the user's unique ear canal and fitted into the ear canal by an audiologist or physician. Note that the ECA casing touches external ear and ear canal tissue, and is vented to minimize the occlusion effect.

3. Sound Processor*:* The Sound Processor rests over the external ear and functions to receive and amplify the sound vibrations and transform the sound pressure into electrical signals which are received by the ECA. The Sound Processor consists of three parts, which are housed and attached with commercially available ABS plastic components commonly used by the hearing aid industry.

a. Microphone:
The microphone is capable of, but not limited to, a frequency response of 100 Hz - 10 kHz.

b. Preamplifier:
The Sound Processor employs a dual channel wide-dynamic-range input compression system (DynamEQ-II) that separates incoming signals into high and low frequency channels which can be independently adjusted prior to recombination and amplification.

c. Power amplifier*:*
The Class D power amplifier is designed to provide extended battery life. Battery current is required to perform at the following levels: for reference test position, less than or equal to 1.0 mA; for the full VC position, less than or equal to 2.8 mA.

Sound Processor Operation*:* The Sound Processor's output may be controlled by the user or audiologist. Users may operate a volume control, while audiologists may adjust the Sound Processor's three trimmers for high frequency, low frequency, and the threshold knee point.

Device Accessories:
Five accessory sets assist in operation and maintenance of the SOUNDTEC Direct System device:

1. Search Coil Set: The SOUNDTEC Search Coil is an optional device that may be used to verify the function of the implant to electromagnetic stimulation. This device emits a 2000 Hz electromagnetic signal that should be perceived by implanted patients as a 2000 Hz tone.

2. Test Coupler Set*:* This set contains the SOUNDTEC Test Coupler, as well as fitting and testing models of the Sound Processors to aid audiologists in assisting patients prior to Direct System fitting, at fitting, and during field-testing.

3. Surgeon's Set*:* This set contains the stainless steel surgical instruments and sterilization tray necessary to perform the implantation procedure for the magnetic implant. These non-magnetic instruments are comparable to most existing magnetic instrumentation used in stapedectomy procedures.

4. Clinician's Set*:* This set is used by the audiologist to take the deep ear impression of the patient's ear canal for the fitting of the ECA. It includes impression material, impression gun and canula assemblies, impression oil and materials, batteries and impression template and materials.

5. User's Set*:* This set is provided to each user for maintenance of the external portions of the system. It includes a drying agent, cleaning spray, batteries, and storage pouch.

VI. Alternative Practices and Procedures

Alternative practices and procedures available to SOUNDTEC® Direct System users include acoustic hearing aids and other implantable middle ear hearing devices. Hearing aids can be worn in a variety of styles including behind-the-ear, in-the-ear, in-the-canal, or completely-in-the-canal.

VII. Marketing History

The SOUNDTEC® Direct System has not been marketed in the United States or any foreign country.

VIII. Potential Adverse Effects of the Device on Health

Surgery of the middle ear requires manipulation of the ossicular bones (malleus, incus, and stapes) and exposes the inner ear to the risk of surgical trauma. Serious complications may arise either during or after surgery that may include, but are not limited to: sensorineural or conductive deafness due to trauma during surgery; granular inflammatory lesions; device displacement after surgery due to development of scar tissue; damage to the incus; non-functioning implant; and infection after surgery. Additional surgery may be required to correct these conditions, if possible.

There may also be numbness, swelling or discomfort around the ear, the possibility of facial paresis, and/or the disturbance of balance or taste, but they are usually transient and resolve within a few weeks after surgery.

Refer to Table I, Summary of Adverse Events Reported.

IX. Summary of Preclinical Studies

The objective of the preclinical studies was to provide reasonable assurance of the safety of the SOUNDTEC® Direct System prior to clinical testing. In addition, the sponsor provided a Declaration of Conformity to the following consensus standards:

Table 1 - Consensus Standards

Title of Standard	Standard ID	Date	Agency
Metals			
Standard Specifications for Unalloyed Titanium for Surgical Implant Applications	ASTM F67-95	1995	American Society of Testing of Material
Standard Specifications for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications	ASTM F136-98	1998	American Society of Testing of Material
Biological and Sterilization			
Biological Evaluation of Medical devices—Part 5: Tests for *in vitro* cytotoxicity	ISO 10993-5; 1993	1993	International Organization for Standardization
Biological Evaluation of Medical Devices, Volume 4	AAMI; 1997	1997	American Association for Medical Instrumentation
Biological Evaluation of Medical Devices—Part 10: Tests for Irritation and Sensitization	ISO 10993-10; 1995	1995	International Organization for Standardization
Biological Evaluation of Medical Devices—Part 7: Ethylene Oxide Sterilization Residuals	ISO 10993-7	1995	International Organization for Standardization
Rabbit Pyrogen Test	USP XXIV	1/2000	US Pharmacopia
Sterility Testing/Direct Transfer to Test Media	USP XXII; XXI	1985	US Pharmacopia
Cytotoxicity-Elution Testing	USP XXIV	1/2000	US Pharmacopia
FMEA/Risk Analysis			
Medical Devices—Risk Analysis	EN 1441	10/1997	European Committee for Standardization
Analysis Techniques for System Reliability—Procedure for Failure Mode and Effects Analysis (FMEA)	CEI/IEC 812	1985	International Electrotechnical Commission
Engineering			
Procedure 1A-Performance Test for Individually Packaged-Products Weighing 150 lb. (68kg) or Less	ISTA Procedure 1A	7/2000	International Safe Transit Association (ISTA)

Title of Standard	Standard ID	Date	Agency
Method 1014.10 Seal	Mil Std – 883D	3/1995	United States Department of Defense
Environmental Testing Part 2: Test Z/ABDM Climatic Sequence	IEC 68-2-61, Environmental Testing Part 2: TestZ/ABDM: Climatic Sequence	1991	International Electrotechnical Commission
Basic Environmental Testing Procedures Part 2: Tests	IEC 68-2-32	1975	International Electrotechnical Commission
Medical Electrical Equipment—Part 1: General Requirements for Safety	EN 60601-1-2; 1993	1993	European Committee for Standardization
Limits and Methods of Measurement of Radio Disturbance Characteristics of Industrial, Scientific, and Medical (ISM) Radio-Frequency Equipment	EN 55011 Class B Group 1	1997	European Committee for Standardization

A. Biocompatibility

1. Direct System Implant

All body-contacting materials in the implant have been chosen for their acceptability in other implantable medical devices. Each material has shown a well-characterized level of biological response to long-term clinical use.

The SOUNDTEC® Direct System implant consists of a rare earth magnet encapsulated in a hermetically sealed titanium canister, which is implanted on the incudo-stapedial (IS) joint of the middle ear. The canister material and wire form attachment ring is constructed of titanium specifically used for surgical implant applications.

2. Direct System Earmold/Coil Assembly

A series of *in vitro* and *in vivo* studies were performed on the acrylic material of the Earmold/Coil assembly to demonstrate that the materials were biocompatible. All testing was conducted in conformance with 21 CFR 58 – *Good Laboratory Practice for Nonclinical Laboratory Studies.*

The Earmold/Coil Assembly is a custom made device, which is molded in the shape of the subject's external ear and ear canal. It is inserted and fitted into the subject's ear canal.

The Earmold/Coil Assembly incorporates standard acrylic polymers, which are used in every day hearing aid applications worldwide. This is a methacrylate mixture which is indicated for medical use.

The materials were tested in final finished form and passed the following tests: Cytotoxicity, Sensitization, and Irritation.

3. Direct System Sound Processor

A series of *in vitro* and *in vivo* studies were conducted on the medical grade ABS plastic and other material of the Sound Processor to demonstrate that the materials were biocompatible. All testing was conducted in conformance with 21 CFR 58 – *Good Laboratory Practice for Nonclinical Laboratory Studies.*

The materials were tested in final finished form and passed the following tests: Cytotoxicity, Sensitization, and Irritation.

Biocompatibility Conclusion

The test results showed no acute toxicological concerns and support the safety of the SOUNDTEC® Direct System for its intended use.

B. Microbiology

Testing consisting of the sterility assurance of the sterilization process, ethylene oxide sterilization residual, and pyrogenicity determination were performed on the Direct System. All testing passed appropriate International standards.

C. Mechanical Testing

The SOUNDTEC® Direct System was mechanically tested to verify the design criteria and device performance with respect to the device's properties and specifications in supporting the safety and effectiveness of its profile. Where applicable, test protocols were written to recognized, consensus standards. Other test protocols were drafted to verify design criteria and device performance unique to the SOUNDTEC® Direct System as necessary.

1. Direct System Implant

The Direct System implant was tested in final finished form and passed testing for: hermeticity and weld evaluation, magnet-wireform separation test, wireform cycle test and wireform implant deflection test.

2. Direct System Earmold/Coil Assembly

The Direct System Sound Processor was tested in finished form and passed testing for: environmental testing, shock and vibration testing and life expectancy tests.

3. Direct System Sound Processor

The Direct System performance was evaluated at various input levels over the frequency range of 125 Hz to 8000 Hz. This evaluation

showed that the Sound Processor provides flexibility and smooth transition across the range of values for each control and adequate compensation across the frequency range.

D. Electrical Testing

The SOUNDTEC® Direct System was electrically tested to verify the design criteria and device performance with respect to the device's properties and specifications in supporting the safety and effectiveness of its profile. Where applicable, test protocols were written to recognized consensus standards. Other test protocols, were drafted to verify design criteria and device performance unique to the SOUNDTEC® Direct System as necessary

1. Direct System Implant

Where appropriate, the Direct System implant was tested in final finished form and passed testing for: Electromagnetic Immunity, Electromagnetic Emissions, and Wireless Device Compatibility Tests.

SOUNDTEC® commissioned an independent laboratory to evaluate the electrical safety of the Direct System. The laboratory tested the Direct System to EN 60601-1-2 and EN55011 and determined that it was free from safety hazards and in compliance with requirements of the standards.

The evaluation of the SOUNDTEC® Direct System for compatibility with digital cell phones, theft detecting devices, and metal detectors, showed that the sound processor demonstrated a good degree of immunity to electromagnetic interference. The initial investigation indicates that exposure to magnetic fields that could be experienced in the everyday environment generally do not create distorted or abnormal output from the sound processor. Also it was determined that the SOUNDTEC® Direct System does not adversely affect the theft detection devices tested.

The ability to hear clearly on a digital cell phone does appear to be dependent on the type of phone used, as well as, the positioning of the cell phone antenna to the sound processor body. In most cases it was found that the use of the digital cell phone did not distort the sound quality presented to the user.

2. Direct System Earmold/Coil Assembly

Where appropriate, the Direct System Earmold/Coil Assembly was tested in final finished form and passed testing for: Electromagnetic Immunity, Electromagnetic Emissions, and Wireless Device Compatibility Tests.

3. Direct System Sound Processor

Where appropriate, the Direct System Sound Processor was tested in final finished form and passed testing for: Electromagnetic Immunity, Electromagnetic Emissions, and Wireless Device Compatibility Tests.

E. Failure Mode Effects Analysis (FMEA)/Hazard Analysis/Failure Rate Prediction

FMEA was evaluated to the component and process levels of the implant, Sound Processor and the Earmold/Coil Assembly. The evaluation extended to incorporate degree of severity of the consequences, likelihood of occurrence, and their detectability. Failure rate was calculated for the Sound Processor to be 1.92×10^7 Hours and the Earmold/Coil Assembly was calculated to be 3.96×10^7 Hours.

The risk analysis procedure incorporated the requirements of European standard EN 1441. The analysis includes identification of each hazard, causes, effects, probability of failure, criticality determination, acceptability of risk, and (remarks) mitigation. It was determined that all stated risks and hazards were acceptable.

F. Life Testing

A series of *in vitro* were performed on the Direct System under accelerated vibrational conditions of 125 dB and 2000Hz, simulating a loud aggressive sound. In addition, real time shelf life studies were conducted on finished Direct System implants in their final packaging configuration.

1. Accelerated Life Testing

Accelerated life testing of vibrational conditions of 125 dB and 2000Hz was conducted on the Direct System implant. The results showed no signs of degradation after 1500 hours of continuous operation.

2. Shelf Life Testing

SOUNDTEC® Direct System Implant is packaged in a polyethylene foam shield which is placed inside a polyethylene teraphtalate glycol (PETG) modified blister tray. The PETG tray is sealed with a Tyvek lid/label. The Tyvek tray assembly with the implant and foam are placed inside a Tyvek Mylar pouch and is sealed with a Chevron seal.

The testing standards used were USP. Samples analyzed for testing were selected on the basis of real-time aging for shelf life. Accelerated testing was not used.

Test results demonstrated packaging integrity of 60 months of shelf life.

ISTA (International Safe Transit Association) packaging tests were performed to determine the ability of SOUNDTEC® packaging to protect the product during shipping and handling. Test results showed less than

10 % package degradation as allowed in the ISTA project 1A specification.

G. MRI Testing

Temporal bone studies and Finite Element Analysis (FEA) performed for SOUNDTEC® demonstrates that the SOUNDTEC® Direct System implant is not affected by the magnetic fields generated by MRI instruments. In a 0.3 Tesla Open MRI unit the forces seen by the implant were 20% of the forces reported for the closed MRI, which showed a force of 0.74 gms.

Analysis of induction heating resulted in a value of 2.9×10^{-2} K temperature rise for a 10-minute exposure in a 2 T field.

For a field gradient as high as 3T/mm, linear forces would be approximately 1 gm. For a 1.5 Tesla MRI the torsional forces would be approximately 50 **g-cm.** The torsional forces are approximately 23% below the force required to damage the I.S. joint.

As animal/clinical testing has not been conducted, SOUNDTEC warns users against undergoing a MRI examination, entering a room where MRI exams are performed, or come into close proximity to other sources of strong magnetic fields

H. Accessory Testing

The search coil is the device used to determine the general location of the implant relative to the tympanic membrane surface. It provides evidence the implant can be activated electromagnetically. The information gained through a search coil examination provides a landmark to align the coil when fabricating the Earmold/Coil Assembly.

The test coupler is a device that is used to test the Sound Processor and Earmold/Coil Assembly in the same way that hearing aids are tested using a hearing aid analyzer.

The Search Coil was found to be an acceptable instrument to locate and to determine alignment of the implant. Failure rate for the Search coil was calculated to be 4.88×10^{6} Hours and the Test Coupler 4.49×10^{7} Hours.

I. Software Verification/Validation and Statement Regarding Year 2000 Compliance

The SOUNDTEC® Direct System is not software driven.

J. Animal Studies

For purposes of evaluation, an animal test was conducted with the SOUNDTEC® Direct System in guinea pigs to establish the safety of the device while residing in the middle ear.

The Direct System was simulated in the animal model with a proportionately comparable 24 kt gold Implantable Hearing Device (IHD) prosthesis. The response of the guinea pig incus to the prosthesis was examined at 3 and 6 months post implant.

The results showed no adverse effects associated with the implant. Histological analysis showed no evidence of inflammatory response, excess middle ear fluid, and erosion of the bone in the incudo-stapedial area.

The evidence from this animal study results is consistent with a claim of safety as there were no notable histopathology.

Conclusions of Preclinical Studies

The results of the preclinical studies provided reasonable assurance that the SOUNDTEC® Direct System was safe for clinical studies and implantation in humans for its intended use.

X. Summary of Clinical Studies

A. Study Objectives

The study objectives were to determine whether the SOUNDTEC® Direct System provided a level of useful sound perception (functional gain) and improved subject's satisfaction (self-assessment questionnaires) without having a clinically significant affect upon the patient's residual hearing (air-conduction thresholds).

The study hypotheses represent primary and secondary study objectives. The primary objective is addressed by a quantitative endpoint measure, which provides objective criteria for evaluating the study hypotheses. Secondary objectives are addressed with objective and descriptive statistical methods that evaluate the risks and benefits of the device. Endpoint measures are intended to support specific claims of safety and efficacy.

B. Study Design

The clinical study was designed as a single-subject, repeated measures investigation in which each subject served as her or his own control. The study methods applied a variety of standard, well-known and accepted audiologic measurement techniques.

Phase II of the study has been conducted as a multi-center prospective trial comparing subjects' aided pre-implant hearing aid (PHA) to the SOUNDTEC Direct System.

The investigation involves pre-treatment assessment, implant intervention, healing, and post treatment evaluation for each subject as follows:

COURSE OF STUDY	TIME LINE
PRE TREATMENT	Week 1-2
Medical and Audiometric Evaluation	
Post informed consent waiting period	

IMPLANT INTERVENTION..... Week 3

POST IMPLANT HEALING PERIOD ..... Week 3-13

SOUND PROCESSSOR FITTING..... Week 13

ACCOMMODATION PERIOD..... Weeks 13-23

POST TREATMENT EVALUATION..... Weeks 23-24

LONG TERM FOLLOW UP ..... Post Approval (36 and 52 weeks)

This investigation's primary comparisons were made at approximately 20 weeks post implant. Long-term (post approval) follow-up data will be obtained at approximately 36 and 52 weeks post implant. Those subjects who fit the eligibility criteria and consented to participate in the study were consecutively enrolled into the study, regardless of gender or ethnic origin. Analysis and statistical comparisons of outcomes between baseline and 20 weeks later was used as the basis for determining the safety of Direct System, and for determining quantitative differences in the efficacy of Direct System compared to the PHA.

C. Study Population

A total of one hundred–three (103) subjects with moderate to severe sensorineural hearing loss were implanted with the Direct System at ten (10) implanting sites, described below:

Implanting Site Locations

Site Location	Number of Subjects
Integris Baptist Medical Center; Oklahoma City, OK	**20**
University of Washington; Seattle, WA	**9**
Dartmouth Hitchcock Medical Center; Lebanon, NH	**17**
University of Texas Medical Branch; Galveston, TX	**2**
Memphis Surgery Center; Memphis, TN	**17**
University of Texas Southwestern Medical Center; Dallas, TX	**6**
Fairview University Medical Center; Minneapolis, MN	**5**
Marshfield Clinic; Marshfield, WI	**9**

Presbyterian Medical Center Albuquerque, NM	**7**
Wake Forest University, Winston Salem, NC	**11**
Total	**103**

The majority of subjects in the study were male (68 of 103 or 66%). The average age was 65.1 years (median 67.0 years). The average duration of hearing loss was 15.4 ± 10.8 years. The etiology of hearing loss was unknown for most (51 of 103 or 50%) of the group, while noise (31 of 103 or 30%) was the second leading cause of hearing loss in the study population. The right ear was chosen for implant in a large number (62 of 103 or 60%) of the cases. Nearly all of the subjects (88 of 103 or 85%) were binaural hearing aid users. In addition, the study subjects have been hearing aid users for an average of 7.1 years while the average time of use of the baseline hearing aid was 3.7 years.

D. Study Period

The Investigational Device Exemption (IDE) was approved in January 1998 under G970299. The investigation consisted of two phases with Phase I (Pilot study) including five (5) subjects implanted at one site. Enrollment in the pivotal multi-center study began in March 1999 and included one hundred three (103) subjects implanted in ten (10) centers throughout the United States.

Ninety-five of the 103 subjects (92%) have completed the 20-week assessment as of April 2001. Thirty-three of the 95 subjects (35%) that completed the 20-week follow-up have also completed their 36-week assessment testing. In addition, 12 of the 95 subjects (13%) have completed their 52-week follow-up.

E. Inclusion and Exclusion Criteria

Inclusion Criteria:

- Bilateral symmetrical sensorineural hearing loss (high frequency pure tone average (HFPTA) of 1000, 2000, 4000 Hz within 15 dB of each other)
- Conformance with audiometric threshold profile

Audiometric Inclusion Criteria

Frequency (Hz)	Loss (HL-dB)
250	0-50
500	0-60
1000	10-70
2000	35-75
3000	50-75

4000	50-80
6000	40-100

- Bone conduction audiometric thresholds within 10 dB of air conduction thresholds
- High frequency pure tone average (HFPTA = average of 1000,
- 2000, and 4000 Hz) of 35-70dB HL
- Score of ≥ 60% on NU-6 words under headphones bilaterally
- Duration of hearing loss ≥ 2 years without fluctuation
- Subjects will have at least six months of recent hearing aid use
- Subjects will have at least 45 days of recent use of NAL-R compliant hearing aid
- 21-80 years of age
- Absence of otitis media, external otitis or retrocochlear pathology
- Subjects will have sufficient cognitive and English language skills and motivation to comply with the study protocol.
- Subjects will have adequate ear canal size to accommodate Earmold/Coil Assembly
- Dissatisfied hearing aid user
- Signed Subject Informed Consent Form

Exclusion Criteria

- Malformation or inflammation of the external and/or middle ear
- Perforated tympanic membrane
- Acute otitis media
- Otosclerosis
- Previous middle ear surgery that has destroyed the IS joint or the integrity of the ossicular chain
- Disabling tinnitus
- Medical condition which affects healing or may have an associated hearing loss
- Retrocochlear hearing loss
- Asymmetrical hearing loss (difference in HFPTA of 1000, 2000, and 4000Hz of greater than 15dB)
- Conductive hearing loss
- Fluctuating hearing loss
- Unilateral hearing loss

- Hearing loss duration of less than 2 years
- Threshold responses outside the audiometric threshold profile defined for the study
- Score of less than 60% on NU 6 (50) words under headphones
- Personal hearing aid use of less than 6 months
- Personal hearing aid does not meet study's NAL-R criteria
- Age less than 21 years and older than 80 years
- Use of NAL-R compliant hearing aid for less than 45 days
- Satisfied hearing aid wearer
- Inadequate ear canal size to accommodate Earmold/Coil Assembly
- Refusal to comply with monaural use requirements of the study protocol
- Insufficient cognitive skills, motivation or English language skills to comply with study protocol

F. Findings

1. Safety

The primary outcome for measuring safety was the effect of the device on residual hearing. In addition safety was evaluated in terms of the incidence of anticipated adverse events, and implant device failures and revisions.

One hundred-three (103) subjects underwent the implant procedure with the SOUNDTEC® Direct System implant. The following clinical study summary is based on ninety-five (95) subjects who had completed 20-week assessments. The assessment compared preoperative results with an optimally fit acoustic hearing aid in the ear to be implanted to post operative results with the SOUNDTEC® Direct System. "Optimally fit" as defined by the clinical study included insertion gain matching using National Acoustic Laboratories-Revised (NAL-R) prescriptive target ranges (±5 dB for 500, 1000, and 2000 Hz and ± 12 dB for 3000 and 4000 Hz) and evidence of improvement in aided benefit.

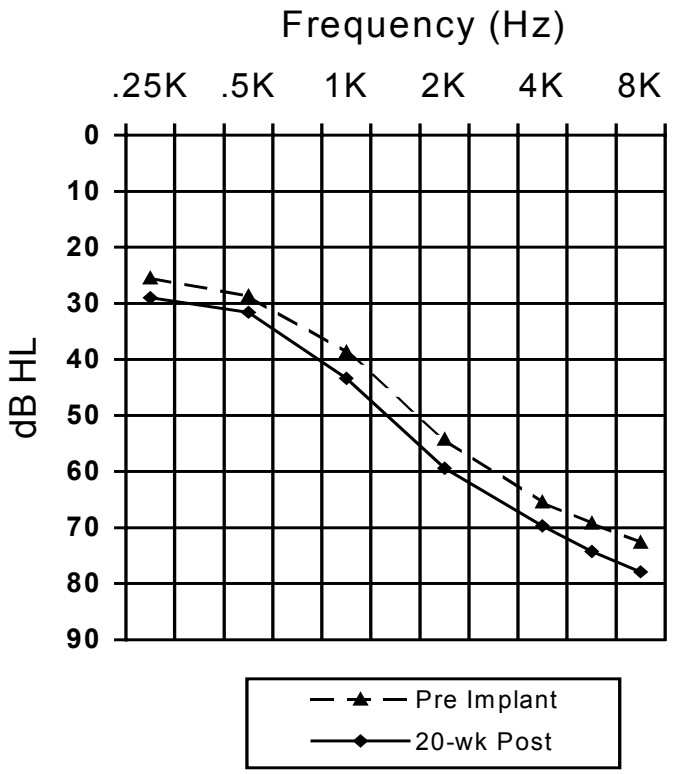
Subjects were tested to find hearing thresholds, sound field thresholds, speech testing in quiet and noise, aided benefit, and subject perceptions.

A. Residual Hearing

1. Air Conduction Thresholds

For most subjects (85 of 95 or 89.5%), residual hearing with the Direct System was not significantly affected. Average decrease in air conduction thresholds at 20 weeks was 4.2 dB across the frequency range of 250 to 8000 Hz. Average bone conduction thresholds decreased by 1.1 dB. Few subjects (10 of 95 or 10.5%) had greater than 10 dB of change. Eight of 95 subjects (8%) experienced a change between 10 to 15 dB in hearing thresholds and 2 of 95 subjects (2%) experienced a change greater than 15 dB.
Refer to Figure 1.

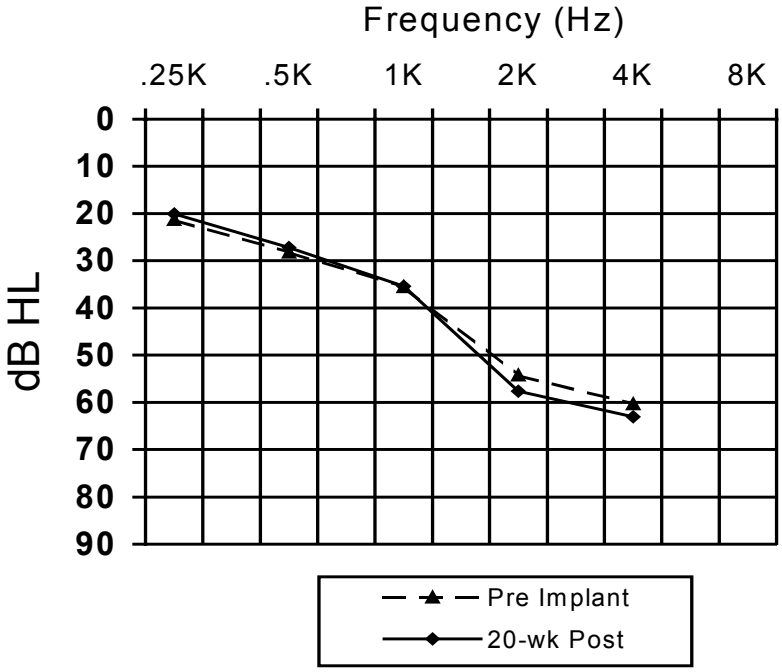
Figure 1
Air Conduction Thresholds



2. Bone Conduction Thresholds

Figure 2 shows the bone conduction thresholds over the audiometric frequency range (250-4000 Hz) for the pre-implant and 20 week post-implant conditions. The average changes across these frequencies post-implant compared to the pre-implant condition are 1.1 dB. Most subjects (91 of 95 or 96%) showed less than an average of 10 dB of change in bone conduction thresholds. Few (4 of 95 or 4%) showed an average decrease between 10-15 dB of change. No subjects showed greater than 15 dB of change for bone conduction thresholds.

Figure 2
Bone Conduction Thresholds



B. Adverse Events Related to the Device

1. Summarized in Table 1 are the adverse events reported on a total of 103 subjects reported as of April 4, 2001.

Four (4) subjects were reported as having serious adverse events, all of which were determined by a physician to be "definitely" unrelated to the device. The events included a cardiovascular disorder, carcinoma, and two (2) deaths.

Table 1. Adverse Events Reported (n=103 Subjects)

Description	No. Reported	No. Resolved
Abnormal Ear Sensation[1]	1	1
Device Noise/Electromagnetic Interfence[2]	15	12
Ear Disorder[3]	1	1
Ear Mold Assembly Failure[4]	7	7
Ear Pain[5]	30	28
Increased Hearing Loss[6]	1	0
Hematoma Ear[7]	9	9
Infection[8]	4	4
Outer Ear Irritation[9]	14	14
Paresthesia[10]	1	1
Processor Failure[11]	13	12

Skin Irritation[12]	3	3
Taste Perversion[13]	3	2
Tinnitus[14]	1	0
Transient Balance Involvement[15]	5	5
Tympanic Membrane Damage[16]	6	5

[1] Investigator reported abnormal ear sensation consisting of fullness; event resolved during the normal healing period after implant.
[2] Engineering analysis determined these events to be associated with the Printed Circuit Board (PCB) assembly operation. The operation has been modified and validated. Low levels of EMI have been found to be dependent upon the location and strength of the electromagnetic source.
Three events reported as unresolved were due to their intermittent nature and are being monitored by the Investigator at the subjects' next visits.
[3] Investigator reported middle ear effusion; event resolved during the normal healing period after implant.
[4] Engineering analysis of the ECAs resulted in improved manufacturing processes and controls that have been implemented to eliminate systematic failures.
[5] These events were related to the operative procedure or to the ECA fitting. In most of the cases these events resolved through longer healing periods post-implant or through ECA modifications. The Investigator is continuing to monitor the 2 subjects whose events were reported as unresolved.
[6] Audiological data indicated that the hearing loss appears to be conductive. Investigator reported that he will continue to monitor the subject.
[7] Each of the reported hematomas resolved through normal healing.
[8] The infections also included Otitis Media (2) and Otitis Externa (2). Each of the reported events resolved through otologic management.
[9] Outer ear irritation consisted of ear irritation (7), ear canal abrasion (2), ear edema (2), ear inflammation (2), and ear abrasion external (1).
[10] The investigator reported this event as a transient neurological effect.
[11] Processor failures were determined to be associated with the PCB assembly operation. The operation has been modified and validated. Analysis of the unresolved processor failure was in-process at the submission of this data.
[12] Several observations of skin irritation were reported, including Eczema (2) and Pruritis (1). The investigators noted that each event was resolved.
[13] Taste perversion can be related to the severing or irritation of the chorda tympani nerve during the implantation procedure. Resolution occurred spontaneously without treatment or surgical intervention. One case remains unresolved and will be monitored by the Investigator.
[14] Subject medical records noted a past history of tinnitus. This case will be monitored by the Investigator.
[15] Transient balance involvement comprised of reports of dizziness (1), nausea (1), vertigo (2), and vomiting (1). Each event resolved spontaneously.
[16] Four reported events were resolved through surgical intervention and one event resolved without intervention. One event is not resolved and the Investigator is monitoring the subject.

(Non-serious adverse events unrelated to the device are not included in Table 1. These events consisted of: Unconfirmed ECA/Sound Processor failures (16), broken ECAs due to user abuse, improper use, or adjustments that damaged the device (7), tooth disorder (1), and infection in the non-implant ear (1)).

2. Implant Device Failures and Replacements

There were no implant device failures, revisions or replacements reported in this study. Some failures of the external Sound Processor and Earmold Coil Assembly were noted and analyzed. Improved manufacturing processes and controls have been implemented to eliminate systematic failures.

3. Study Discontinuation

There have been no study discontinuations. No subjects have asked for their implants to be removed.

2. Effectiveness

The primary evaluation of efficacy is measured by comparing the difference in the amount of functional gain provided by the subject's optimally fit hearing aid to the SOUNDTEC Direct System. In addition efficacy shall be determined by the improved perceived benefit and satisfaction of the Direct System compared to the subject's optimally fit hearing aid.

A. Increased Functional Gain

The SOUNDTEC® Direct System provided 7.9 dB additional functional gain when comparing the subject's acoustic hearing aid performance to that of the SOUNDTEC® Direct System at the 20 week assessment. The DDHS demonstrated a statistically significant improvement in averaged aided sound field thresholds and functional gain from 500 – 4000 Hz.

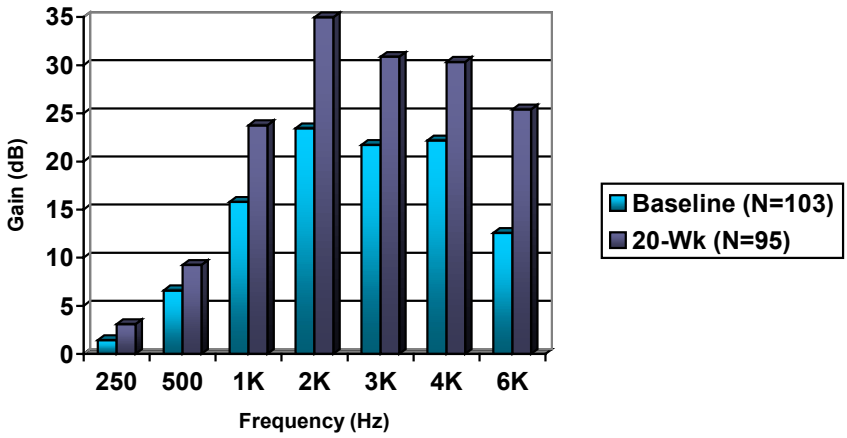
At 36 and 52 weeks, the additional functional gain was 7.9 dB and 7.0 dB, respectively.

All three (3) time points, showed a statistically significant gain in average functional gain (each p-value < 0.05, Paired t-test).

Refer to Figure 3.

Figure 3

Functional Gain
for Baseline and 20-Wk Post-Implant



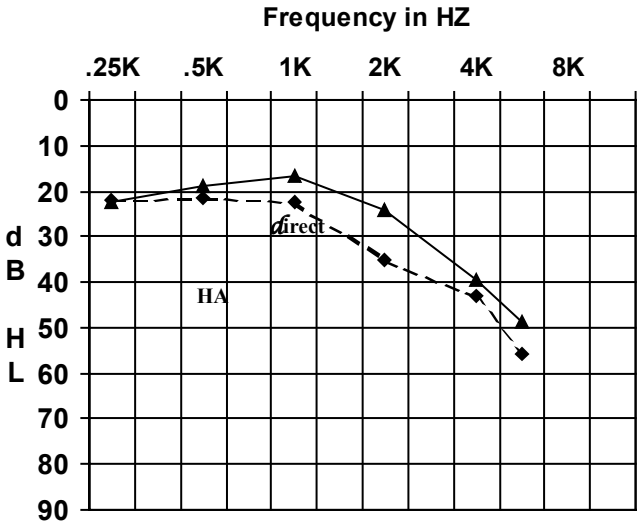
Additional functional gain is needed to compensate for the residual hearing threshold change. Aided thresholds are improved with the Direct System regardless of the decrease in residual hearing. Individual results will vary.

Figure 4 shows aided thresholds comparing the Direct System to the acoustic hearing aid.

Figure 4

Aided Thresholds in Sound Field

25% Avg. Improvement for 500-4000 Hz



A similar analysis was performed for the high frequency average of 2000, 3000 and 4000 Hz (referred to in the protocol as the High Frequency Warble Tone Average-HFWTA of functional gain). The average improvement in the high frequency range at 20 weeks compared to performance with an acoustic hearing aid is 9.6 dB.

At 36 and 52 weeks, the average improvement in HFWTA is 9.2 dB and 10.8 dB, respectively.

At each of the three (3) time points, the improvement from performance with an acoustic hearing aid achieved statistical significance (each p-value < 0.05, Paired t-test).

B. Change in Articulation Index

A secondary outcome measuring audibility is the Articulation Index (AI) and was assessed at pre-implant and 20 weeks. The AI was used to calculate the level of audibility based on aided hearing thresholds. The average improvement in Articulation Index scores comparing performance with the Direct System to the acoustic hearing aid was 11.9%. The improvement was statistically significant (p-value < 0.05, Paired t-test).

C. Speech Perception Results

There are two (2) additional secondary efficacy measures of performance using audiometric speech tests. These consist of the NU-6 (50-item word list) and the Speech Perception In Noise

(SPIN) test. Tables 2 and 3 show the results on the aided NU-6 test and the SPIN (aided, low predictability sentences-raw scores) test. The results indicate average improvements with the DDHS on the NU-6 performance of 5.3%, 5.0%, and 12.2% across the 20, 36, and 52-week assessments, respectively. The NU-6 improvement from the acoustic hearing aid to the Direct System was statistically significant at the 20 and 52-week follow-ups. On average, SPIN scores were similar pre-implant and post-implant at the 20 and 36 week assessments.

Table 2 - Summary of NU-6 Aided Word Test (mean±SD)

	NU-6 (% Correct)	Paired t-test p-value
Baseline (N=103) Optimally Fit Hearing Aid	76.8±16.6	N/A
20 Weeks (N=95) Direct System	82.1±11.9	N/A
Improvement	5.3±16.6	0.0026 *
36 Weeks (N=33) Direct System	83.8±10.3	N/A
Improvement	5.0±15.4	0.0700 **
52 Weeks (N=12) Direct System	86.7±9.9	N/A
Improvement	12.2±12.6	0.0066 *

* Statistically Significant (Paired t-test, p-value < 0.05)

** Borderline Statistically Significant (Paired t-test. 0.05 < p-value < 0.10)

Reference: Clinical Report Appendices B.23-B.24

The average change in SPIN aided, low predictability sentences at 20 weeks was –0.1 words. For the 36 and 52-week follow-ups, the average improvements were 0.1 words and 4.2 words. The SPIN improvement from baseline to the 52-week follow-up was statistically significant (p-value = 0.0135, Paired t-test).

Table 3 - Summary of SPIN Aided, Low Predictability Test (mean±SD)

	SPIN Aided, Low Predictability (# Correct out of 25)	Paired t-test p-value
Baseline (N=102) Optimally Fit Hearing Aid	9.8±5.4	N/A
20 Weeks (N=95) SOUNDTEC Direct	10.0±5.0	N/A
Improvement	-0.1±5.9	0.8743
36 Weeks (N=22) SOUNDTEC Direct	9.9±5.9	N/A
Improvement	0.1±8.2	0.9664
52 Weeks (N=12) SOUNDTEC Direct	12.2±6.2	N/A
Improvement	4.2±5.0	0.0135 *

* Statistically Significant

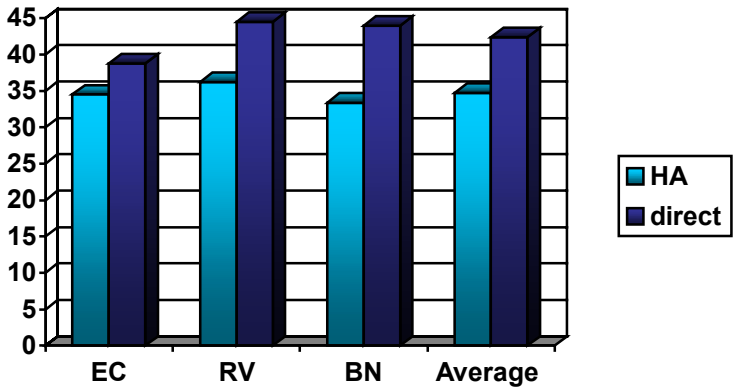
Reference: Clinical Report Appendices B.25-B.26

D. Improvements in Perceived Benefit in Various Listening Situations

The Abbreviated Profile of Hearing Aid Benefit (APHAB) is a questionnaire used to assess the subject's perceived performance benefit in three areas: Ease of Communication (EC), Reverberation (RV), and Background Noise (BN). These were reported at pre-implant using the subject's acoustic hearing aid and at 20 weeks using the SOUNDTEC® Direct System. On average, the hearing aid condition provided a score of 34.7 points of aided benefit and the Direct System 20 week condition provided a score of 42.2 points of aided benefit for the three subscales. While individual results varied, the average improvement across the three subscales is 7.2 ±19.9 points of improvement of aided benefit, which is statistically significant.

Figure 5 shows the comparison between acoustic hearing aids and the Direct System for each of the three areas.

Figure 5
Aided Benefit (APHAB)



E. Reduction in Feedback, Occlusion, and Distortion

A second questionnaire, the Hough Ear Institute Profile (HEIP), was used to examine the following areas: satisfaction, acoustic feedback, perception of speech quality, occlusion, and tinnitus. The 20 Week HEIP results with the SOUNDTEC® Direct System were compared to the subject's acoustic hearing aid values in 94 subjects (one subject of 95 completed all testing except the HEIP due to an error in test administration). All of these results were found to be statistically significant.

- Out of 94 subjects responding, 84 of those subjects (89%) preferred the DDHS in terms of overall satisfaction. Satisfaction was measured by a four point scale with four being very satisfied and one being not at all satisfied. Using this scoring method, satisfaction with the Direct System increased by an average of 30.8% (median = 16.7%) from the subject's acoustic hearing aid (p-value < 0.0001, Paired t-test).

- Sixty-three of 94 subjects (67%) reported having feedback with their acoustic hearing aid. At 20 weeks, only 8 (9%) subjects reported feedback using the SOUNDTEC® Direct System (p-value < 0.0001, McNemar's Test).

- Out of 94 subjects responding, 93 subjects (99%) preferred the Direct System as having the least amount of feedback.

- Subject Perceived Quality of Speech was rated on a 7-point scale. The mean percentage increase relative to the subject's optimally fit hearing aid equaled 27.8% (median = 19.2%) for the SOUNDTEC® Direct System (p-value< 0.0001, Paired t-test).

- Out of 94 subjects responding, 84 of those subjects (89%) responded that they preferred the Direct System over their acoustic hearing aids in the area of sound quality.
- Fifty of 92 subjects (54%) reported occlusion with their acoustic hearing aids. 21 of 92 subjects (23%) reported occlusion using the SOUNDTEC® Direct System (p-value < 0.0001, McNemar's Test). (Two of 94 subjects did not respond to the question concerning occlusion).
- Twenty-one of 41 (51%) subjects reporting tinnitus pre-implant reported that their hearing aid decreased their perception of tinnitus.
- Twenty of 30 (67%) subjects reporting tinnitus post-implant reported that the Direct System decreased their perception of tinnitus.

F. Gender Analysis

There were 68 males and 35 females that participated in the clinical study, accounting for 66% and 34% respectively. The higher proportion of male patients in the study is consistent with the higher incidence of male sensorineural hearing loss in the United States.

Although the potential exists for minor differences in physiological response by gender for the target population, the minimal number of clinically significant findings does not indicate that gender differences are of clinical importance for this device.

G. Conclusions of Clinical Study

The results from this study demonstrate reasonable assurance of evidence of safety and effectiveness. There are no serious safety concerns with the SOUNDTEC® Direct System. A majority of the adverse events reported were expected, transient, and occurred at low incidence rates. There were no implant device replacements or surgical revisions necessary.

The effectiveness of the SOUNDTEC® Direct System is as follows: functional gain, speech measures, and subjective evaluations reached statistically significant improvements when comparing preoperative results with an optimally fit acoustic hearing aid to a 20 week assessment with the SOUNDTEC Direct System.

XI. Conclusion Drawn from the Studies

The results of the preclinical and clinical studies provide reasonable assurance of the safety and effectiveness of the SOUNDTEC® Direct System for the patient population, sensorineural hearing loss characteristics, and specified indications for use.

XII. Panel Recommmendation

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Ear, Nose and Throat Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. CDRH Decision

Labeling provided includes two patient brochures. One is intended to provide Information to the patient to assist in making the decision whether to have the device implanted and the second is to assist the patient in the use of the device after implantation.

The manufacturing facility was inspected on May 17, 2001 and found to be in compliance with device Quality Systems Regulations.

FDA issued an approval order on September 7, 2001

XIII. Approval Specifications

- Directions for use: See the labeling.
- Warnings, hazards to health from use of device: See Indications, Contraindications, Warnings, and Precautions in the labeling.
- Post approval requirements and restrictions: See Approval Order.