DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 28 1997

Martin Starkie
Customer Service Representative
AM Hearing Limited
Faraday Road
Crawley, West Sussex,
England

Re: K973579
AM14, AM152AGC, AM152 , AGC-D, AM240PPL, AM240PPI, AM240HF, AM260AGC, AM260HF, AM2600HM, AM260K-AMP, AM260XP, AM262T-AGS, AM300XP, AM300AGC, AM300HF, AM300K-AMP, AM400PP, AM400PPL, AM500PP,AM510, AM530, AM550, AM800PPL, AM800T-AGS Hearing Aid
Dated: September 19, 1997
Received: September 19, 1997
Regulatory class: I
21 CFR 874.3300/Procode: 77 ESD

Dear Ms. Starkie:

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.

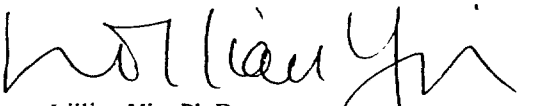
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, 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.

While your device has been deemed substantially equivalent to other legally marketed hearing aids, please be advised that electromagnetic interference from digital cellular telephones, as well as from other sources is increasingly becoming a concern. Typically, this interference takes the form of a buzzing sound that can range from annoying to very loud and may render a hearing aid temporarily ineffective for the wearer. Because electromagnetic interference may affect your device, you may be asked to test for electromagnetic compatibility in the future. In this interim period, we encourage you to modify your device labeling to inform practitioners and users of the potential for electromagnetic interference. Please be aware that a 510(k) submission is required for any claims that infer that your device is compatible with potential sources of electromagnetic interference, such as "compatible with digital cellular telephones", and that data supporting such claims is necessary.

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/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): K973579

Device Name: AM 14

Indications For Use:

A. General Indications:

The indication for use of the air conduction hearing aids in this submission is to amplify sound for individuals with impaired hearing. The devices are indicated for individuals with losses in the following category(ies). (Check appropriate space(s)):

Severity:	Configuration:	Other
X 1. Slight	___ 1. High Frequency - Precipitously Sloping	___ 1. Low tolerance To Loudness
X 2. Mild	X 2. Gradually Sloping	X 2. WITH LOUD INPUT LEVELS POSSIBLE
X 3. Moderate	___ 3. Reverse Slope	___ 3. ASYMMETRICAL
___ 4. Severe	X 4. Flat	X High tolerance to Loudness
___ 5. Profound	___ 5. Other_____	

B. Specific Indications (Only if appropriate.):
(Most psychoacoustic indications such as improved speech intelligibility in background noise, must be supported by clinical data.)

1.

2.

3.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973579

Restricted device (per 21 CFR 801.420 & 21 CFR 801.421)

510(k) Number (if known): K 973579

Device Name: AM 150 PP

Indications For Use:

A. General Indications:

The indication for use of the air conduction hearing aids in this submission is to amplify sound for individuals with impaired hearing. The devices are indicated for individuals with losses in the following category(ies). (Check appropriate space(s)):

Severity:	Configuration:	Other
___1. Slight	X 1. High Frequency - Precipitously Sloping	___1. Low tolerance To Loudness
___2. Mild	X 2. Gradually Sloping	X 2. High tolerance to LOUDNESS
X 3. Moderate	___3. Reverse Slope	___3. _____
X 4. Severe	___4. Flat	
___5. Profound	X 5. Other precipitous beginning @ 1KHz.	

B. Specific Indications (Only if appropriate.):
(Most psychoacoustic indications such as improved speech intelligibility in background noise, must be supported by clinical data.)

1. Good for patients with conductive HL.

2.

3.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David C. Kessler

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973579

Restricted device (per 21 CFR 801.420 & 21 CFR 801.421)

510(k) Number (if known): K 973 579

Device Name: MM 152 AGC

Indications For Use:

A. General Indications:

The indication for use of the air conduction hearing aids in this submission is to amplify sound for individuals with impaired hearing. The devices are indicated for individuals with losses in the following category(ies). (Check appropriate space(s)):

Severity:	Configuration:	Other
___1. Slight	X 1. High Frequency - Precipitously Sloping	X 1. Low tolerance To Loudness
X 2. Mild	X 2. Gradually Sloping	___2. _____
X 3. Moderate	___3. Reverse Slope	___3. _____
X 4. Severe	X 4. Flat	
___5. Profound	X 5. Other precipitous from 1KHz on	

B. Specific Indications (Only if appropriate.):
(Most psychoacoustic indications such as improved speech intelligibility in background noise, must be supported by clinical data.)

1. Ideal for patients with sensorineural HL.

2. Good for those with narrow dynamic range

3.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lehman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973579

Restricted device (per 21 CFR 801.420 & 21 CFR 801.421)

510(k) Number (if known): K973579

Device Name: AM 152 AGC-1

Indications For Use:

A. General Indications:

The indication for use of the air conduction hearing aids in this submission is to amplify sound for individuals with impaired hearing. The devices are indicated for individuals with losses in the following category(ies). (Check appropriate space(s)):

Severity:	Configuration:	Other
___1. Slight	___1. High Frequency - Precipitously Sloping	X 1. Low tolerance To Loudness
X 2. Mild	X 2. Gradually Sloping	___2. _____
X 3. Moderate	___3. Reverse Slope	___3. _____
X 4. Severe	X 4. Flat	
___5. Profound	X 5. Other precipitous from 1K/Hz ->	

B. Specific Indications (Only if appropriate.):
(Most psychoacoustic indications such as improved speech intelligibility in background noise, must be supported by clinical data.)

1. Ideal for patients with sensorineural HL.

2. Those who have a narrow dynamic range.

3.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David C. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973579

Restricted device (per 21 CFR 801.420 & 21 CFR 801.421)

510(k) Number (if known): K973579

Device Name: AM 240 PPL

Indications For Use:

A. General Indications:

The indication for use of the air conduction hearing aids in this submission is to amplify sound for individuals with impaired hearing. The devices are indicated for individuals with losses in the following category(ies). (Check appropriate space(s)):

Severity:	Configuration:	Other
___ 1. Slight	X 1. High Frequency - Precipitously Sloping	X 1. Low tolerance To Loudness
___ 2. Mild	X 2. Gradually Sloping	X 2. High tolerance to LOUDNESS
X 3. Moderate	X 3. Reverse Slope	___ 3. _____
X 4. Severe	X 4. Flat	
X 5. Profound	X 5. Other SCOOP	

B. Specific Indications (Only if appropriate.):
(Most psychoacoustic indications such as improved speech intelligibility in background noise, must be supported by clinical data.)

1. Good for severe - profound HL. whether conductive mixed or SNHL.

2.

3.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973579

Restricted device (per 21 CFR 801.420 & 21 CFR 801.421)

510(k) Number (if known): K973579

Device Name: AM 240 PPi

Indications For Use:

A. General Indications:

The indication for use of the air conduction hearing aids in this submission is to amplify sound for individuals with impaired hearing. The devices are indicated for individuals with losses in the following category(ies). (Check appropriate space(s)):

Severity:	Configuration:	Other
___1. Slight	X 1. High Frequency – Precipitously Sloping	X 1. Low tolerance To Loudness
___2. Mild	X 2. Gradually Sloping	X 2. High tolerance to Loudness
X 3. Moderate	___3. Reverse Slope	___3.
X 4. Severe	___4. Flat	
___5. Profound	X 5. Other precipitous, scoop	

B. Specific Indications (Only if appropriate.):
(Most psychoacoustic indications such as improved speech intelligibility in background noise, must be supported by clinical data.)

1. Good for moderate - severe mixed or conductive HL.

2.

3.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973579

Restricted device (per 21 CFR 801.420 & 21 CFR 801.421)

510(k) Number (if known): K973579

Device Name: AM 240 HF

Indications For Use:

A. General Indications:

The indication for use of the air conduction hearing aids in this submission is to amplify sound for individuals with impaired hearing. The devices are indicated for individuals with losses in the following category(ies). (Check appropriate space(s)):

Severity:	Configuration:	Other
___1. Slight	X 1. High Frequency - Precipitously Sloping	X 1. Low tolerance To Loudness
___2. Mild	___2. Gradually Sloping	___2. _____
X 3. Moderate	___3. Reverse Slope	___3. _____
___4. Severe	___4. Flat	
___5. Profound	X 5. Other precipitous @ 1.5K/Hz	

B. Specific Indications (Only if appropriate.):
(Most psychoacoustic indications such as improved speech intelligibility in background noise, must be supported by clinical data.)

1. Benefits a mild-moderate Sensorineural HL.

2.

3.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lewis

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973579

Restricted device (per 21 CFR 801.420 & 21 CFR 801.421)

510(k) Number (if known): K 973579

Device Name: AM 260 AGC

Indications For Use:

A. General Indications:

The indication for use of the air conduction hearing aids in this submission is to amplify sound for individuals with impaired hearing. The devices are indicated for individuals with losses in the following category(ies). (Check appropriate space(s)):

Severity:	Configuration:	Other
___1. Slight	___1. High Frequency - Precipitously Sloping	X 1. Low tolerance To Loudness
X 2. Mild	X 2. Gradually Sloping	___2. _____
X 3. Moderate	___3. Reverse Slope	___3. _____
___4. Severe	X 4. Flat	
___5. Profound	___5. Other_____	

B. Specific Indications (Only if appropriate.):
(Most psychoacoustic indications such as improved speech intelligibility in background noise, must be supported by clinical data.)

1. Good for Sensorineural hearing Loss.

2.

3.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973579

Restricted device (per 21 CFR 801.420 & 21 CFR 801.421)

510(k) Number (if known): K 973 579

Device Name: AM 260 HF

Indications For Use:

A. General Indications:

The indication for use of the air conduction hearing aids in this submission is to amplify sound for individuals with impaired hearing. The devices are indicated for individuals with losses in the following category(ies). (Check appropriate space(s)):

Severity:	Configuration:	Other
___1. Slight	X 1. High Frequency - Precipitously Sloping	X 1. Low tolerance To Loudness
X 2. Mild	X 2. Gradually Sloping	___2. _____
X 3. Moderate	___3. Reverse Slope	___3. _____
___4. Severe	___4. Flat	
___5. Profound	___5. Other_____	

B. Specific Indications (Only if appropriate.):
(Most psychoacoustic indications such as improved speech intelligibility in background noise, must be supported by clinical data.)

1. Good for Sensorineural hearing Loss.

2.

3.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lazzara

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973579

Restricted device (per 21 CFR 801.420 & 21 CFR 801.421)

510(k) Number (if known): K 973579

Device Name: AM 260 CHM

Indications For Use:

A. General Indications:

The indication for use of the air conduction hearing aids in this submission is to amplify sound for individuals with impaired hearing. The devices are indicated for individuals with losses in the following category(ies). (Check appropriate space(s)):

Severity:	Configuration:	Other
___1. Slight	___1. High Frequency - Precipitously Sloping	X 1. Low tolerance To Loudness
X 2. Mild	X 2. Gradually Sloping	___2. _____
X 3. Moderate	X 3. Reverse Slope	___3. _____
X 4. Severe	X 4. Flat	
___5. Profound	___5. Other_____	

B. Specific Indications (Only if appropriate.):
(Most psychoacoustic indications such as improved speech intelligibility in background noise, must be supported by clinical data.)

1.

2.

3.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Hoyson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973579

Restricted device (per 21 CFR 801.420 & 21 CFR 801.421)

510(k) Number (if known): K973579

Device Name: AM 260 K-AMP

Indications For Use:

A. General Indications:

The indication for use of the air conduction hearing aids in this submission is to amplify sound for individuals with impaired hearing. The devices are indicated for individuals with losses in the following category(ies). (Check appropriate space(s)):

Severity:	Configuration:	Other
___1. Slight	___1. High Frequency - Precipitously Sloping	X 1. Low tolerance To Loudness
X 2. Mild	X 2. Gradually Sloping	___2. _____
X 3. Moderate	___3. Reverse Slope	___3. _____
X . Severe	X 4. Flat	
___5. Profound	___5. Other_____	

B. Specific Indications (Only if appropriate.):
(Most psychoacoustic indications such as improved speech intelligibility in background noise, must be supported by clinical data.)

1. SPECIFICALLY FOR THOSE WITH RECRUITMENT.

2. IDEAL FOR NEW HEARING AID USERS.

3.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973579

Restricted device (per 21 CFR 801.420 & 21 CFR 801.421)

510(k) Number (if known): K973579

Device Name: AM 260 XP

Indications For Use:

A. General Indications:

The indication for use of the air conduction hearing aids in this submission is to amplify sound for individuals with impaired hearing. The devices are indicated for individuals with losses in the following category(ies). (Check appropriate space(s)):

Severity:	Configuration:	Other
___1. Slight	___1. High Frequency - Precipitously Sloping	X 1. Low tolerance To Loudness
___2. Mild	X 2. Gradually Sloping	___2. _____
X 3. Moderate	___3. Reverse Slope	___3. _____
X 4. Severe	X 4. Flat	
___5. Profound	X 5. Other scoop, precipitous	

B. Specific Indications (Only if appropriate.):
(Most psychoacoustic indications such as improved speech intelligibility in background noise, must be supported by clinical data.)

1. Good for mod-severe sensorineural HL.

2.

3.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Feigal

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973579

Restricted device (per 21 CFR 801.420 & 21 CFR 801.421)

510(k) Number (if known): K 973579

Device Name: AM 262 TACS

Indications For Use:

A. General Indications:

The indication for use of the air conduction hearing aids in this submission is to amplify sound for individuals with impaired hearing. The devices are indicated for individuals with losses in the following category(ies). (Check appropriate space(s)):

Severity:	Configuration:	Other
___1. Slight	___1. High Frequency - Precipitously Sloping	X 1. Low tolerance To Loudness
X 2. Mild	X 2. Gradually Sloping	___2. _____
X 3. Moderate	___3. Reverse Slope	___3. _____
X 4. Severe	___4. Flat	
___5. Profound	___5. Other precipitous beginning @ 1 kHz →	

B. Specific Indications (Only if appropriate.):
(Most psychoacoustic indications such as improved speech intelligibility in background noise, must be supported by clinical data.)

1. Appropriate HA for those exposed to continuous noise as well as
2. short and abrupt sudden noises.
3.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segarra
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973579

Restricted device (per 21 CFR 801.420 & 21 CFR 801.421)

510(k) Number (if known): K 973 579

Device Name: AM 300 XP

Indications For Use:

A. General Indications:

The indication for use of the air conduction hearing aids in this submission is to amplify sound for individuals with impaired hearing. The devices are indicated for individuals with losses in the following category(ies). (Check appropriate space(s)):

Severity:	Configuration:	Other
___1. Slight	X 1. High Frequency - Precipitously Sloping	X 1. Low tolerance To Loudness
X 2. Mild	X 2. Gradually Sloping	___2. _____
X 3. Moderate	___3. Reverse Slope	___3. _____
X 4. Severe	___4. Flat	
___5. Profound	___5. Others - / -	

B. Specific Indications (Only if appropriate.):
(Most psychoacoustic indications such as improved speech intelligibility in background noise, must be supported by clinical data.)

1. MINIATURE BTE (GOOD) FOR NON ADULTS

2. (GOOD for mod - sev SNHL.

3.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Legvold

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973579

Restricted device (per 21 CFR 801.420 & 21 CFR 801.421)

510(k) Number (if known): K973579

Device Name: Apt 30 AHC

Indications For Use:

A. General Indications:

The indication for use of the air conduction hearing aids in this submission is to amplify sound for individuals with impaired hearing. The devices are indicated for individuals with losses in the following category(ies). (Check appropriate space(s)):

Severity:	Configuration:	Other
___1. Slight	___1. High Frequency - Precipitously Sloping	X 1. Low tolerance To Loudness
X 2. Mild	X 2. Gradually Sloping	___2. _____
X 3. Moderate	___3. Reverse Slope	___3. _____
X 4. Severe	X 4. Flat	
___5. Profound	___5. Other_____	

B. Specific Indications (Only if appropriate.):
(Most psychoacoustic indications such as improved speech intelligibility in background noise, must be supported by clinical data.)

1. Miniature size - good for mild - moderate

2. Good for SNR

3.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973579

Restricted device (per 21 CFR 801.420 & 21 CFR 801.421)

510(k) Number (if known): K973579

Device Name: AM 300 HF

Indications For Use:

A. General Indications:

The indication for use of the air conduction hearing aids in this submission is to amplify sound for individuals with impaired hearing. The devices are indicated for individuals with losses in the following category(ies). (Check appropriate space(s)):

Severity:	Configuration:	Other
___1. Slight	X 1. High Frequency - Precipitously Sloping	___1. Low tolerance To Loudness
X 2. Mild	___2. Gradually Sloping	X 2. high frequency emphe
X 3. Moderate	___3. Reverse Slope	X 3. high tolerance to Loudness
___4. Severe	___4. Flat	
___5. Profound	___5. Other_____	

B. Specific Indications (Only if appropriate.):
(Most psychoacoustic indications such as improved speech intelligibility in background noise, must be supported by clinical data.)

1.

2.

3.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lehman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973579

Restricted device (per 21 CFR 801.420 & 21 CFR 801.421)

510(k) Number (if known): K973579

Device Name: AM 300 K-AMP

Indications For Use:

A. General Indications:

The indication for use of the air conduction hearing aids in this submission is to amplify sound for individuals with impaired hearing. The devices are indicated for individuals with losses in the following category(ies). (Check appropriate space(s)):

Severity:	Configuration:	Other
___1. Slight	___1. High Frequency - Precipitously Sloping	X 1. Low tolerance To Loudness
___2. Mild	X 2. Gradually Sloping	___2. _____
X 3. Moderate	___3. Reverse Slope	___3. _____
X 4. Severe	X 4. Flat	
___5. Profound	___5. Other_____	

B. Specific Indications (Only if appropriate.):
(Most psychoacoustic indications such as improved speech intelligibility in background noise, must be supported by clinical data.)

1. Specifically for those w/ reinforcement.

2. Ideal for new hearing aid users.

3.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973579

Restricted device (per 21 CFR 801.420 & 21 CFR 801.421)

510(k) Number (if known): K973579

Device Name: AM 400AP

Indications For Use:

A. General Indications:

The indication for use of the air conduction hearing aids in this submission is to amplify sound for individuals with impaired hearing. The devices are indicated for individuals with losses in the following category(ies). (Check appropriate space(s)):

Severity:	Configuration:	Other
___ 1. Slight	___ 1. High Frequency - Precipitously Sloping	X 1. Low tolerance To Loudness
___ 2. Mild	X 2. Gradually Sloping	X 2. High tolerance to Loudness
X 3. Moderate	X 3. Reverse Slope	___ 3. _____
X 4. Severe	X 4. Flat	
X 5. Profound	X 5. Other Scoop	

B. Specific Indications (Only if appropriate.):
(Most psychoacoustic indications such as improved speech intelligibility in background noise, must be supported by clinical data.)

1. Good for profound conductive HL.

2.

3.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lagomarsino

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973579

Restricted device (per 21 CFR 801.420 & 21 CFR 801.421)

510(k) Number (if known): K973579

Device Name: AM 400PPL

Indications For Use:

A. General Indications:

The indication for use of the air conduction hearing aids in this submission is to amplify sound for individuals with impaired hearing. The devices are indicated for individuals with losses in the following category(ies). (Check appropriate space(s)):

Severity:	Configuration:	Other
___ 1. Slight	___ 1. High Frequency - Precipitously Sloping	X 1. Low tolerance To Loudness
___ 2. Mild	X 2. Gradually Sloping	X 2. High tolerance to LOUDNESS
X 3. Moderate	X 3. Reverse Slope	___ 3. _____
X 4. Severe	X 4. Flat	
X 5. Profound	X 5. Other Scoop	

B. Specific Indications (Only if appropriate.):
(Most psychoacoustic indications such as improved speech intelligibility in background noise, must be supported by clinical data.)

1. Good for profound conductive HL

2.

3.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Feigenson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973579

Restricted device (per 21 CFR 801.420 & 21 CFR 801.421)

510(k) Number (if known): K973579

Device Name: AM500 AP

Indications For Use.

A. General Indications:

The indication for use of the air conduction hearing aids in this submission is to amplify sound for individuals with impaired hearing. The devices are indicated for individuals with losses in the following category(ies). (Check appropriate space(s)):

Severity:	Configuration:	Other
___1. Slight	___1. High Frequency - Precipitously Sloping	X 1. Low tolerance To Loudness
X 2. Mild	X 2. Gradually Sloping	___2. _____
X 3. Moderate	___3. Reverse Slope	___3. _____
X 4. Severe	X 4. Flat	
___5. Profound	___5. Other_____	

B. Specific Indications (Only if appropriate.):
(Most psychoacoustic indications such as improved speech intelligibility in background noise, must be supported by clinical data.)

1. Good for mild - severe HL because gain control can be manipulated
2. to give less gain for those who don't need.
3.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Hegemann

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973579

Restricted device (per 21 CFR 801.420 & 21 CFR 801.421)

510(k) Number (if known): K973579

Device Name: Am1 510

Indications For Use:

A. General Indications:

The indication for use of the air conduction hearing aids in this submission is to amplify sound for individuals with impaired hearing. The devices are indicated for individuals with losses in the following category(ies). (Check appropriate space(s)):

Severity:	Configuration:	Other
___1. Slight	___1. High Frequency - Precipitously Sloping	___1. Low tolerance To Loudness
X 2. Mild	X 2. Gradually Sloping	X 2. high tolerance to loudness
X 3. Moderate	___3. Reverse Slope	___3. _____
___4. Severe	X 4. Flat	
___5. Profound	___5. Other_____	

B. Specific Indications (Only if appropriate.):
(Most psychoacoustic indications such as improved speech intelligibility in background noise, must be supported by clinical data.)

1.

2.

3.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973579

Restricted device (per 21 CFR 801.420 & 21 CFR 801.421)

510(k) Number (if known): K973579

Device Name: AM 530

Indications For Use:

A. General Indications:

The indication for use of the air conduction hearing aids in this submission is to amplify sound for individuals with impaired hearing. The devices are indicated for individuals with losses in the following category(ies). (Check appropriate space(s)):

Severity:	Configuration:	Other
___1. Slight	___1. High Frequency - Precipitously Sloping	___1. Low tolerance To Loudness
___2. Mild	X 2. Gradually Sloping	X 2. High tolerance to Loudness
X 3. Moderate	___3. Reverse Slope	___3. _____
X 4. Severe	___4. Flat	
___5. Profound	X 5. Other precipitous @ 1KHz-on	

B. Specific Indications (Only if appropriate.):
(Most psychoacoustic indications such as improved speech intelligibility in background noise, must be supported by clinical data.)

1.

2.

3.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Edward A. Legerton

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973579

Restricted device (per 21 CFR 801.420 & 21 CFR 801.421)

510(k) Number (if known): K973579

Device Name: AVA 550

Indications For Use:

A. General Indications:

The indication for use of the air conduction hearing aids in this submission is to amplify sound for individuals with impaired hearing. The devices are indicated for individuals with losses in the following category(ies). (Check appropriate space(s)):

Severity:	Configuration:	Other
___1. Slight	___1. High Frequency - Precipitously Sloping	___1. Low tolerance To Loudness
___2. Mild	X 2. Gradually Sloping	X 2. high tolerance to Loudness
X 3. Moderate	___3. Reverse Slope	___3. _____
X 4. Severe	X 4. Flat	
___5. Profound	___5. Other_____	

B. Specific Indications (Only if appropriate.):
(Most psychoacoustic indications such as improved speech intelligibility in background noise, must be supported by clinical data.)

1.

2.

3.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973579

Restricted device (per 21 CFR 801.420 & 21 CFR 801.421)

510(k) Number (if known): K973579

Device Name: AM SCOOP

Indications For Use:

A. General Indications:

The indication for use of the air conduction hearing aids in this submission is to amplify sound for individuals with impaired hearing. The devices are indicated for individuals with losses in the following category(ies). (Check appropriate space(s)):

Severity:	Configuration:	Other
___1. Slight	___1. High Frequency - Precipitously Sloping	X 1. Low tolerance To Loudness
___2. Mild	X 2. Gradually Sloping	X 2. High tolerance to Loudness
___3. Moderate	X 3. Reverse Slope	___3. _____
X 4. Severe	X 4. Flat	
X 5. Profound	X 5. Other SCOOP	

B. Specific Indications (Only if appropriate.):
(Most psychoacoustic indications such as improved speech intelligibility in background noise, must be supported by clinical data.)

1. Good for profound conductive HL.

2.

3.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Edward C. Legerton

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K97-3579

Restricted device (per 21 CFR 801.420 & 21 CFR 801.421)

510(k) Number (if known): K973579

Device Name: AM800 T-AGS

Indications For Use:

A. General Indications:

The indication for use of the air conduction hearing aids in this submission is to amplify sound for individuals with impaired hearing. The devices are indicated for individuals with losses in the following category(ies). (Check appropriate space(s)):

Severity:	Configuration:	Other
___1. Slight	___1. High Frequency - Precipitously Sloping	X 1. Low tolerance To Loudness
___2. Mild	X 2. Gradually Sloping	___2. _____
___3. Moderate	X 3. Reverse Slope	___3. _____
X 4. Severe	X 4. Flat	
X 5. Profound	X 5. Other scoop	

B. Specific Indications (Only if appropriate.):
(Most psychoacoustic indications such as improved speech intelligibility in background noise, must be supported by clinical data.)

1. Appropriate for those with HL exposed to continuous as well as abrupt loud noise similarly.

2.

3.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Lymn

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973579

Restricted device (per 21 CFR 801.420 & 21 CFR 801.421)