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501(k) Summary

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The following information is submitted for approval as required by Title 21, Code of Federal Regulations, Subchapter H-Medical Devices, Subpart E, Paragraph 807.81-Premarket Notification.

Device names:
Trade names: Intrastar pre-wired faceplate in-the-ear hearing aid models:
SP-W "A1"
SP-W "K1"
SP-W "K4"
"G1"
"G3"

Common name: hearing aid pre-wired faceplate

Classification name: hearing aid

Substantial equivalence: The functions and design of the above-named devices are substantially equivalent to existing conventional devices installed in in-the-ear hearing aids currently available through commercial distribution, such as:

510(k) Number	Trade/Proprietary Name	Manufacturer
K884871 (Attachment 3)	Resound In-The-Ear Hearing Enhancement System	Resound Corp.
K902846 (Attachment 4)	PRIZM Hearing System	AudioScience, Inc.

Description: Descriptions of the device functions, scientific concepts, and physical and performance characteristics of the above-mentioned Intrastar models are set forth in Attachments 1 and 2.

Use: Segi Hearing Aid Co. is introducing into commercial distribution the above-mentioned Intrastar models of in-the-ear hearing aid pre-wired faceplates. The intended use of these models is to amplify sound pressure waves and transmit the signal to the external ear through the medium of air to compensate for impaired hearing. Their function and design are substantially equivalent to those installed in existing conventional in-the-ear hearing aids currently available through commercial distribution.

Comparison of technological characteristics:

	Intrastar All models	Resound K884871	AudioScience K902846
Maximum SSPL90	124.8-133.2 dB	114 dB SPL	122 dB SPL
HF Avg.	119.6-126.4 dB	112 dB SPL	114 dB SPL
Full on gain	38.3-55.4 dB	54 dB max	54 dB
Reference test gain	38.3-49.4 dB		54 dB
Frequency range	200-8000 Hz	200-7000 Hz	100-6800 Hz
THD 500 Hz	1.6-5.2%		<5%
THD 800 Hz	1.8-13.4%		<5%
THD 1600 Hz	0.3-7.7%		<5%
Equivalent input noise	19.0-29.4 dB	28 dB SPL	21-26 dB
Battery current	0.74-1.37 mA	1.3 mA	2.2 mA