



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

DEC 05 2013

Carole Rogin, President
Hearing Industries Association
1444 I Street, NW, Suite 700
Washington, DC 20005

Re: Docket No. FDA-2013-P-1552 513(e) Reclassification Petition for Wireless Air
Conduction Hearing Aids (21 C.F.R. § 874.3305)

Dear Ms. Rogin:

Your petition, dated November 21, 2013, to the Food and Drug Administration (FDA) requesting reclassification of Wireless Air Conduction Hearing Aids (21 C.F.R. § 874.3305) from class II to class I has been received. If you have any questions about this response, please contact me at (301) 796-6579.

Sincerely,

A handwritten signature in black ink, appearing to read "Jean Olson", is written over a horizontal line.

Jean Olson
CDRH Regulations Staff
Center for Devices and
Radiological Health