

**THE FDA WANTS TO HEAR FROM PATIENTS RE: TREATMENT OPTIONS FOR MODERATE TO SEVERE HEARING LOSS (Implanted hearing devices vs. other treatment options)**

*The FDA is seeking input from patients on their personal experience with their device and benefit-risk tradeoffs related to treatment options.*

**You are welcome to complete this questionnaire, prepared by the American Academy of Audiology in attempt to provide the FDA with comprehensive viewpoints on behalf of patients.**

**Submission Information: COMMENTS ARE DUE ON/BY JULY 2, 2019**

1. The easiest way to submit this information is via mail to:

Dockets Management Staff (HFA-305),  
Docket No. FDA-2019-N-1619  
Food and Drug Administration,  
5630 Fishers Lane, Rm. 1061,  
Rockville, MD 2085

2. To Submit a Comment with Confidential Information:

*To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public docket, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>*

FOR FURTHER INFORMATION CONTACT:

Anindita Saha, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5414, Silver Spring, MD 20993-0002, 301-796-2537.

**AMERICAN ACADEMY OF AUDIOLOGY PATIENT PREFERENCE QUESTIONNAIRE**

**Docket No. FDA-2019-N-1619**

1. Do you wear (circle):

*One hearing aid*

*Two hearing aids*

*CROS or BiCROS*

*One Hybrid Cochlear Implant*

*Two Hybrid Cochlear Implant*

*One Cochlear Implant*

*Two Cochlear Implants*

*One Cochlear implant for single-sided deafness*

*Osseointegrated Hearing Device for single-sided deafness*

*Oseeointegrated Hearing Device for moderate to severe conductive loss, one side*

*Oseeointegrated Hearing Device for moderate to severe conductive loss, both sides*

*Auditory Brainstem Implant/s*

2. Please describe the most important benefits your hearing device provides to you

3. Were there any risks that concerned you when making the decision to obtain your hearing device?

4. What motivated you to move forward with obtaining your hearing device despite identified risks?

5. Would you choose to obtain this type of hearing device again? Why or why not?
  
6. Please describe any barriers that you encountered in receiving your particular device.
  
  
  
  
  
  
  
  
  
  
7. Did your hearing healthcare provider recommend any other device and/or treatment options, and if so, please list/describe them.
  
  
  
  
  
  
  
  
  
  
8. What additional options would you like to access in future models of your chosen device and/or treatment?
  
  
  
  
  
  
  
  
  
  
9. What information would you give to someone making the decision whether or not to get this type of hearing device?