Cochlear Implant Patient Assessment

Evaluation of Candidacy, Performance, and Outcomes

Second Edition

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Preface

Coursework included in the education of student clinicians and educators in the fields of audiology, speech-language pathology, and deaf education tends to focus considerable attention on the history and evolution of cochlear implants, including iterations in implant design, signal processing, and recipient outcomes. This information is infinitely valuable and necessary to understand cochlear implants and to ultimately apply that knowledge to the patient and student. What tends to be overlooked in academic instruction, however, is the applied knowledge base required for cochlear implant patient assessment in everyday clinical practice—something that cannot generally be imparted solely from clinical and educational practicum. Clinicians from around the world have phoned and e-mailed with questions regarding candidate selection, preoperative evaluation protocol, counseling, and postoperative assessment. Questions range from recommending implantation for patients who may not fit the traditional implant candidate profile to sound-field calibration for pre- and postimplant testing to recommendations for additional assessments that may yield diagnostic information not currently provided by the standard battery. Given that the numbers of adult and pediatric implant recipients continue to increase, more clinicians will be expected to gain and maintain a level of experience surrounding the clinical management of this special population. This book can serve as a guidebook, delivering clinically relevant information to audiologists, speech-language pathologists, and deaf educators regarding the assessment tools and therapeutic intervention that are critical during the pre- and postimplant periods.

Acknowledgments

There are a number of individuals to whom I must express my sincerest gratitude for their contributions and assistance in completing this book. First, I would like to individually thank my contributors. Emily Lund, PhD, CCC-SLP, graciously offered her writing and clinical expertise in childhood hearing loss and speech-language pathology for Chapters 4 and 9. Dr. Lund is a rigorous and thoughtful researcher as well as a highly skilled speech-language pathologist. Most of her work has focused on development of language, literacy, and preliteracy skills in children with developmental disabilities, with a particular focus on children with cochlear implants. Dr. Lund is a trusted colleague and I greatly value her opinion and knowledge.

Robert F. Labadie, MD, PhD, MMHC, FACS, offered his valuable clinical and scientific experiences as an otologic surgeon to write Chapter 5. Not only is Dr. Labadie an exceptional surgeon and one of the most critically thinking clinician-scientists that I have ever met, but his lectures on cochlear implant surgery and ear anatomy are the highlight of my cochlear implant class each year! This chapter is a great addition to the second edition.

My Chapter 1 coauthors—Laura Blair, AuD, Patricia B. Macy, MA, and Cedric Navarro—are all so impressive in their expertise regarding implant regulation. They have taught me so much more than I could ever imagine about a dry, yet critically important topic. In fact, I've even come to enjoy reading about regulatory matters. I must also thank AuD students, David Kessler and Andie DeFreese, for providing their valuable assistance with organizing the references for this book.

Special thanks must be extended to my coworkers and colleagues, some of whom volunteered their time to read and provide comments on earlier versions of this work, and all of whom are instrumental in developing, revising, and implementing our clinical assessment protocols. They are dedicated to best practices and their patients reap the benefits! Specifically I want to thank Linsey Sunderhaus, AuD, Susan Amberg, AuD, Jourdan Holder, AuD, Bob Dwyer, AuD, Kelley Corcoran, AuD, Sara Unrein, AuD, Christine Brown, AuD, Adrian Taylor, AuD, Stephanie Yaras, AuD, Kelsey Hatton, AuD, and Ally Sisler-Dinwiddie, AuD. You are all amazingly talented clinicians and I learn so much from each of you every day.

Finally, and most importantly, I want to thank my family, to whom I am completely committed (despite the fact that my laptop and I appear inseparable). My sons, Levi, Jacob, and Aidan, are a patient group. My boys have always been supportive and continue to be both excited and surprised that Mom could write a book—even if it is a "boring textbook." My husband, Branden, is the best husband this crazy, unorganized, and absent-minded woman could have ever imagined. I am certain that he was handpicked for me and I hope that he accepts my thanks for his love and support and all my apologies for working around the clock.

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Chapter 1

I believe in cochlear implants like I believe that the sun will rise and set each day. In fact, it's not really a belief for me; it's a universal and undisputable truth. One cannot witness the life-altering outcomes for the recipients and their families and not believe wholeheartedly in the power of this technology. My passion for cochlear implants is rivaled only by my enthusiasm for audiology and hearing science. I know of no other field employing a more dedicated and impassioned group of interdisciplinary professionals working toward the common goal of improving hearing outcomes and quality of life for all individuals with hearing loss. It is nothing short of a blessing to be granted the opportunity to work with cochlear implant recipients and their families. Every single patient has impacted me in his or her own special way and I can only hope that I have helped each patient even if only in some small way. Every patient with whom I have worked has educated, humbled, challenged, and inspired me daily, and it is these special individuals who have motivated me to begin, and more importantly to finish, this book. If this work furthers the education of a single student, clinician, teacher, patient, or parent, then I will consider my efforts meaningful. Thus, this work is dedicated to all cochlear implant recipients—young and old—and the professionals who devote their time and talents to ensure that every cochlear implant recipient achieves his or her own highest potential.

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FDA Candidacy for Cochlear Implantation

René H. Gifford, Cedric Navarro, Patricia B. Macy, and Laura Blair

INTRODUCTION

The process of obtaining United States Food and Drug Administration (FDA) approval for biomedical devices is largely a foreign process to the working clinician; however, this process affects every clinician working with individuals who have hearing aids, bone-anchored implants, and/or cochlear implants. There are a number of misconceptions about FDA-labeled indications for adults and children and how these labeled indications affect the clinician's role in determining implant candidacy. Chapter 1 describes aspects concerning FDA approval for biomedical devices, including the nature of the approval process, manufacturer-initiated clinical trials required for approval, as well as the role of the FDA in the regulation of biomedical devices. The chapter concludes with descriptions of the current FDA-labeled criteria for both adult and pediatric populations.

COCHLEAR IMPLANTS: FDA-REGULATED BIOMEDICAL DEVICES

The FDA is responsible for protecting public health by ensuring that certain products are safe and effective, as well as monitoring such products for continued safety. The mission of the FDA is specifically listed as having the "responsibility of protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biologic products, medical devices, our nation's food supply, cosmetics, and products that emit radiation" (FDA, 2018b). To carry out this mission, the FDA is organized into a number of centers and offices, each of which is focused on specific technologies. The center that is responsible for overseeing medical devices, such as cochlear implants, bone-anchored implants, and hearing aids, is the Center of Devices and Radiological Health (CDRH). The CDRH center regulates

all industry that manufactures, repackages, relabels, or imports medical devices in the United States. The CDRH comprises several offices, each of which play a role in the regulation of medical devices. Those offices and their areas of responsibility and roles within the CDRH are shown in Table 1–1.

The U.S. Congress enacted the Medical Device Amendments of 1976 in order to "provide for the safety and effectiveness of medical devices intended for human use." The Medical Device Amendments were added to the Federal Food, Drug, and Cosmetic Act (FD&C Act), which was originally passed in 1938. The Medical Device Amendments established three regulatory classes for medical devices based on the degree of control necessary to ensure safety and effectiveness: classes I, II, and III.

Class I devices are considered low risk to the user. Class I devices constitute 47% of all regulated devices in the U.S. and with the passing of the 21st Century Cures Act (Rep Upton, 2016), 95% of Class I devices are now considered exempt from FDA review. Examples of exempt Class I devices include elastic bandages, patient scales, canes, otoscopes, and hearing aids. Nonexempt Class I devices require that the device manufacturer provide the FDA with premarket notification (510(k)) and listing prohibitions against adulteration and misbranding, and rules for good manufacturing practices. 510(k) premarket notification requires that a manufacturer prove *substantial equivalence* to an existing legally marketed device, which would render it exempt from premarket approval (PMA). Examples of *nonexempt* Class I devices are dental chairs and accessories, wheelchairs, and blood bank supplies.

Class II devices are considered slightly higher risk to the user and constitute 43% of medical devices. Class II devices have the same requirements as nonexempt Class I devices, but additionally require that the manufacturer provide the FDA with performance standards. As with Class I devices, some Class II devices are considered exempt from premarket notification 510(k), including wireless hearing aids, audiometers, and tympanometers, Examples of nonexempt Class II devices

Table 1–1. Responsibilities of the Offices of the Center of Devices and Radiological Health

Office Name	*Area of Responsibility*
Office of Product Evaluation and Quality (OPEQ)	New organization focused on the Total Product Lifecycle of medical devices. This new Super Office combines the prior Office of Device Evaluation, Office of Compliance, and Office of Surveillance and Biometrics ■ Review and approval of Class III devices including design, manufacturing, and quality control changes ■ Review and approval of investigational device exemptions required to collect clinical data in support of a device application ■ Enforces regulatory compliance of industry ■ Monitor safety and efficacy of medicals device through the product life cycle
Office of Policy (OP)	Provides oversight and leadership in the development of regulations, guidances, policies, and procedures concerning medical device and radiation-emitting products
Office of Science and Engineering Laboratories (OSEL)	Scientific review of Class III device applications when requested by either ODE or OC
Office of Strategic Partnerships and Technology Innovation	Provides leadership for all scientific collaborative and emerging technologies

are x-ray systems, bone-anchored implants, and otoacoustic emission equipment.

Class III medical devices are those that are implanted, considered to sustain or support life, and present a potentially unreasonable risk of illness or injury to the recipient (FDA, 2019). Class III devices constitute just 10% of all medical devices in the U.S. Class III devices have all the same requirements as nonexempt Class I and II devices, but additionally require PMA. PMA is a required process of FDA scientific review to ensure safety and effectiveness prior to marketing a device that does not qualify for review based on substantial equivalence. Examples of Class III devices are implantable pacemakers, implanted neuromuscular stimulators, and cochlear implants; thus, cochlear implants are placed in the most highly regulated category of medical devices.

In order to obtain PMA for a new device without substantial equivalence, cochlear implant manufacturers must submit an application to the CDRH for review and consideration (see Table 1–1). The FDA has specific branches within the Office of Product Evaluation and Quality (OPEQ) (Table 1–1), each having the knowledge and professional expertise to review the specific applications. Cochlear implants, middle ear implants, bone-anchored implants, and hearing aids are the responsibility of the Office of Ophthalmic, Anesthesia, Respiratory, ENT, and Dental Devices. The reviewers in this branch are audiologists, hearing scientists, engineers, and ENT physicians/surgeons. OPEQ review panels can be composed of both FDA employees, as well external consultants.

FDA REVIEW PROCESS FOR COCHLEAR IMPLANTS

New Devices

For new cochlear implant internal devices, processors, or significant design changes to internal and/ or external devices for which a *substantially equivalent* device does not exist, the implant manufacturers must submit a PMA application to the FDA, which is reviewed by the Office of Ophthalmic, Anesthesia, Respiratory, ENT, and Dental Devices for consideration. If the ODE reviewers decide that a more detailed scientific review is required in order to determine the safety and efficacy of the product in question, a request will be made for further review by staff from the Office of Science and Engineering Laboratories (OSEL). The OSEL has a staff of scientific reviewers who support all types of medical devices and associated technologies. For cochlear implants, there are OSEL reviewers with specialties in material sciences, mechanical engineering, neurophysiology, and hermeticity.

Existing Devices

If a cochlear implant manufacturer institutes changes to manufacturing and/or quality control for existing devices that affect safety or efficacy, the Office of Ophthalmic, Anesthesia, Respiratory, ENT, and Dental Devices must be notified prior to the initiation of those changes. They review the proposal and can also request a detailed scientific review by OSEL staff. As part of a recent FDA reorganization, the OPEQ was created to focus on the Total Product Lifecycle approach. The prior Offices of Compliance and Surveillance and Biometrics were combined with the Office of Device Evaluation. This approach leverages the expertise and experience of the technical review team to ensure the continued safety and effectiveness of medical devices after approval. OPEQ is responsible for determining whether a manufacturer is in compliance with applicable legal requirements for manufacturing the devices, monitors device recalls, and performs regular facility inspections. OPEQ is also responsible for the evaluation and trending of medical device reports (MDRs). MDRs can be filed by manufacturers, patients, and/or health care providers for medical device failures or adverse events that result in harm.

FDA FUNDING

The FDA application, review, and monitoring of medical devices is intensive both in terms of

Table 1–2. The 2019 Medical Device User Fees Most Applicable for Cochlear Implant Manufacturers

Application Type	*Standard Fee (U.S. $)*	*Small Business Fee (U.S. $)*
Premarket approval (PMA)	$322,147	$80,537
Panel-track supplement	$241,610	$60,403
180-day supplement	$48,322	$12,081
Real-time supplement	$22,550	$5,638
510(k)	$10,953	$2,738
30-day notice	$5,154	$2,577
Annual fee for periodic reporting on a class III device	$11,275	$2,819

the required time and personnel. Although these processes were put in place to ensure the safety and efficacy of medical devices for the American consumer, limited governmental funding is provided in order to carry out its mission and all associated responsibilities. In fiscal year 2019, the U.S. Congress allocated $5.8 billion ($3.2 billion in budget authority) for the FDA's annual budget (FDA, 2018a). According to U.S. census bureau data, the national population in 2019 was 328,247,710 (Worldometers, 2019); thus, the 2019 FDA budget taken from tax dollars (i.e., budget authority) amounted to just $9.75 allocated for each individual living in the U.S. to carry out all responsibilities related to its mission. An obvious question centers on the feasibility of the FDA completing all of its assigned tasks and responsibilities in order to protect and promote public safety on such as limited budget. A second follow-up question centers on the source of the remaining $2.6 billion in the 2019 fiscal year budget. The answer to this question lies in the Medical Device User Fee and Modernization Act.

In 2002, the Medical Device User Fee and Modernization Act (MDUFMA), PL 107-250, was passed to amend the FD&C Act. The most significant provision of the MDUFMA—and that which is most relevant for cochlear implant manufacturers—was that which allowed the FDA to collect user fees for certain premarket reviews. Those PMAs subject to a user fee in accordance with MDUFMA include original PMAs, premarket reports, product development protocols, panel-track supplements, 180-day supplements, and real-time supplements. The user fees are updated annually and are available to the public on the FDA's website. Table 1–2 lists the 2019 medical device user fees most applicable for cochlear implant manufacturers.

DEVICE MODIFICATIONS REQUIRING FDA PMA APPROVAL

It is not the case that user fees are required only when first bringing a cochlear implant to market. Rather, PMA supplements are required in many cases when existing products are modified. One could argue that such tight regulation has the potential to inhibit product growth and development in the field of cochlear implants; however, the FDA explicitly states that the *least burdensome approach* should be taken in all areas of medical device regulation. It is this "least burdensome approach" to regulation that has prompted the development of multiple avenues for supplemental PMA.

A panel-track PMA is a supplement to an already approved PMA for which the manufacturer is requesting a "significant change in design or performance of the device, or a new indication

for use of the device, and for which clinical data will be necessary to provide a reasonable assurance of safety and effectiveness" (FDA, 2018d). For example, any time that the implant manufacturers revise indications or criteria for implantation, they are required to complete a clinical trial, which itself requires FDA approval via investigational device exemption (IDE). Once the IDE is approved, the study is carried out at a number of approved medical centers across the country. Following completion of the study, the manufacturer would then submit an application to the FDA for approval of the revised indications via a panel-track PMA supplement. This process is time and personnel intensive, as well as costly to the manufacturer. It is for these reasons that the manufacturers do not regularly revise labeled indications for implantation despite the widespread knowledge that individuals with less severe hearing losses and better speech recognition scores, as well as children under 12 months of age, benefit from cochlear implants (Chapter 6). Manufacturers are required to submit a 180-day PMA supplement if they intend to make significant changes that affect the safety and effectiveness of the device. Manufacturer-requested changes to components, materials, design, specification, software, color additives, or labeling are considered appropriate for 180-day supplements. In some cases, the FDA may determine that the requested changes are sufficiently complex, requiring a full PMA review by an outside advisory panel. In other cases, the FDA may determine that the proposed changes are minor and thus, a *real-time supplement* may apply. A real-time supplement is one during which the supplement application is reviewed during a meeting or conference call and requires the review of only one scientific discipline.

Cochlear implant manufacturers are required to submit a 30-day notice when they plan to make changes to the manufacturing procedure or changes in the manufacturing method that could affect the safety and effectiveness of their device. A 30-day notice is sufficient as long as the changes do not alter performance, or design specifications, or the designated physical or chemical specifications of a device. Changes to the manufacturing procedure or method of manufacturing that do not affect the safety or effectiveness of the device must be submitted in the periodic report submitted to the FDA that is usually referred to as an annual report.

If a 30-day notice contains device-design or labeling changes in addition to manufacturing changes, the submission will automatically be converted to a 180-day PMA. If the change qualifies for a 30-day notice and complete information has been submitted, the device may be distributed 30 days after the date on which the FDA received the notice. If the information submitted is not adequate, within 30 days of receipt the FDA will provide notice that a 135-day PMA supplement is needed and will describe the additional information or action required for acceptance of the change. If no action occurs within 30 days of the FDA's receipt of the 30-day notice and payment of the user fee, the device may be distributed without further action from the FDA.

LABELED INDICATIONS FOR COCHLEAR IMPLANTATION AND OFF-LABEL USAGE

Current cochlear implant labeled indications (i.e., candidacy criteria) are listed in the physician's package insert that can be found in the packaging of each internal device. Contrary to popular belief, the FDA is not responsible for designating the criteria (indications) for cochlear implantation. Rather, the manufacturers submit an application for PMA outlining the indications for their device. Thus, it is the role of the FDA to either approve or reject the submitted application for PMA and the manufacturer-defined indications. If ultimately approved, the manufacturer-defined indications for implantation are then listed as the FDA criteria for use of that device. These criteria are often referred to as the FDA labeled indications or FDA candidacy criteria; however, the indications are *approved* by the FDA, but not set by the FDA.

What is important for the clinician to recognize in this process is that the FDA governs industry, not the individual clinician nor implant center. The industry—or in this case, the cochlear implant manufacturer—is strictly prohibited from promoting any off-label usage of its device. As is

discussed in Chapter 6, despite considerable evidence in support of expanded cochlear implant candidacy criteria, the implant manufacturers are simply not permitted to recommend implantation for individuals not meeting labeled indications. Clinicians, however, are granted the professional judgment to make clinical determinations for their patients about the suitability of cochlear implant candidacy. In fact, the FDA has provided an information sheet entitled "Off-Label and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices" (FDA, 2018c), which details the conditional approval of off-label usage of medical devices, drugs, and biologics as recommended by licensed clinicians. This information sheet explicitly endorses off-label usage of a marketed medical device when the intent is for clinical practice and not for research purposes. In this document, the FDA counsels that if clinicians recommend off-label usage of a medical device, they have the responsibility to ensure that the following three conditions are met:

1. Be well informed about the product.
2. Base its use on firm scientific rationale and on sound medical evidence.
3. Maintain records of the product's use and effects.

Off-label usage is nothing new in pharmaceuticals, biologics, and medical devices. For pharmaceuticals, estimates are that 20% to 60% are routinely prescribed for off-label usage across all medical specialties (Frattarelli et al., 2014; Jansen, 2011; Smieliauskas, Sharma, Hurley, de Souza, & Shih, 2018; Valeo, 2011; Van Allen, Miyake, Gunn, Behler, & Kohlwes, 2011). In fact, the U.S. Supreme court ruled that off-label use of medical devices is an "accepted and necessary corollary of the FDA's mission" and that clinicians can "prescribe or administer any legally marketed device to a patient without limitation or interference" (Buckman, 2001).

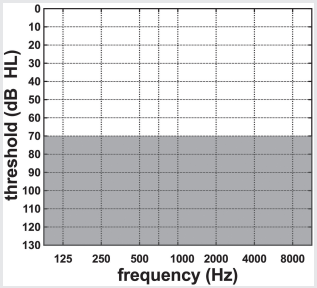
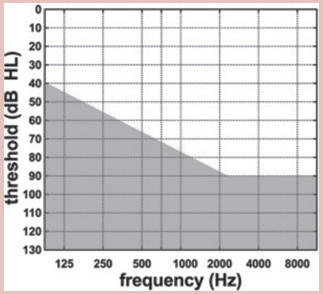
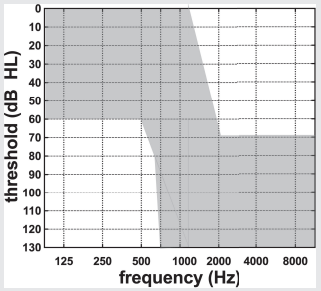
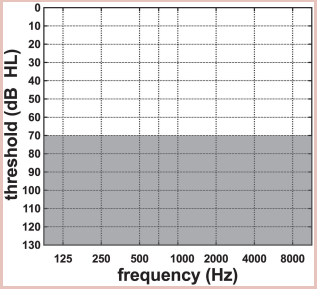
Clinicians may discuss off-label use with individual patients and with colleagues in clinic and at scientific conferences; however, they are not allowed to advertise or market off-label usage to the general public. Such advertising would constitute a violation of the FD&C Act, which states that "a licensed practitioner may not promote a medical device for use(s) for which they have not received FDA clearance." For example, if a cochlear implant center took out an ad stating that individuals with mild to moderate hearing loss might benefit from cochlear implants and should thus consider coming into the center for evaluation, this would be direct violation of FDA policy. Off-label usage of medical devices has become such common practice that even the Tennessee appellate court has ruled that this could be considered "standard of care" (Richardson, 2000). Despite the ubiquity of off-label device usage across all fields, what remains critical is that we as clinicians respect the FDA's position on the stance of off-label cochlear implantation (FDA, 2018c) and consider the needs of each individual patient with our colleagues and members of the interdisciplinary cochlear implant team.

CURRENT COCHLEAR IMPLANT CRITERIA FOR ADULTS AND CHILDREN

Cochlear implant criteria, also referred to as labeled indications for cochlear implantation, have been set independently and differently by each of the cochlear implant manufacturers. Also note that Cochlear and MED-EL have a secondary set of indications for the electric and acoustic stimulation (EAS) systems and MED-EL has a new indication specifically for individuals with single-sided deafness (SSD; see Chapter 6). The current adult and pediatric implant criteria are shown in Tables 1–3 and 1–4, respectively.

Note that there is considerable variability across the manufacturers for both adult and pediatric candidacy. In Table 1–3, for adult indications, Cochlear makes reference to differing speech recognition criteria for the ear to be implanted versus the "best-aided condition." On the other hand, AB, MED-EL, and CMS reference speech recognition performance in the best-aided condition. (Chapter 2 discusses more recent recommendations regarding individual ear testing and focusing on the ear to be implanted.) For all but the EAS systems, aided speech recognition references sentence stimuli for determining candidacy.

Table 1–3. Labeled Indications for Adult Cochlear Implantation as Shown for Advanced Bionics, Cochlear Americas, MED-EL, and CMS.

Adult indications	*Audiometric Thresholds*		*Speech Recognition Performance*
Advanced Bionics HR90K Ultra 3D		severe-to-profound, bilateral sensorineural hearing loss (>70 dB HL)	≤50% for open-set sentence recognition (HINT Sentences)
Cochlear Profile & Profile Plus		moderate to profound hearing loss in the low frequencies and profound (≥90 dB HL) hearing loss in the mid-to-high frequencies	≤50% correct in the ear to be implanted (≤60% in the best-aided condition) on recorded tests of open set sentence recognition
Cochlear Hybrid-L24		thresholds ≤60 dB HL through 500 Hz and ≥70 dB HL for 2000+ Hz	≤60% CNC word recognition in ear to be implanted, ≤80% CNC in contralateral ear
MED-EL Synchrony & Synchrony 2		bilateral severe to profound sensorineural hearing loss (pure-tone average ≥70 dB HL)	≤40% in best-aided listening condition on recorded tests of open-set sentence recognition (HINT sentences)

continues