

FDA每周情报 2026年第32周（中文简体版）

特别资料 FDA官方批准函原文对照集

FDA Official Approval Letter Collection

覆盖周期：2026-07-30 至 2026-08-05。本资料收录本周FDA在全球范围内具有重要监管及产业意义的新药批准、适应症扩展及主要PMA原始批准/专家组审查文件，并特别关注其对中国医药及医疗器械企业的参考价值。每项案例均附有FDA官方批准函（或批准声明）的简体中文翻译、英文原文，以及针对中国相关赛道企业的启示分析。原文如篇幅较长，可能仅节选开头部分。

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OVEPOREXTON (ORZEYFUL)

申请者/企业: TAKEDA PHARMS USA

日期: 2026-08-05

识别编号: NDA220860 (ORIG-1)

FDA官方页面: <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=220860>

对中国企业的启示

武田制药的新药获FDA批准，对中国出海药企的核心参考意义在于，这再次确认了美国市场对真正创新的高准入门槛。国内相关赛道的企业可借此深入研究其完整的临床开发与监管沟通策略，为自身产品的全球注册路径提供参照，同时审慎评估在相应治疗领域中，与此类已获验证的重磅产品进行差异化竞争的可行性。

中文翻译

NDA 220860

新药申请批准函

武田药品美国有限公司

收件人: Mark Swarz

全球注册事务高级总监

500 Kendall Street

Cambridge, MA 02142

尊敬的Mark Swarz先生:

兹涉及贵公司于2025年12月10日收到、并根据《联邦食品、药品和化妆品法案》(FD&C法案)第505(b)条提交的关于Orzeyful (oveporexton) 片的新药申请 (NDA) 及其修正案。

本NDA旨在批准Orzeyful (oveporexton) 片用于治疗成人1型发作性睡病 (伴有猝倒的发作性睡病)。

批准与药品说明书

我们已完成对该申请及其修正案的审评。该申请自本函发出之日起获得批准，可按照随附的经双方商定的药品说明书中的建议使用。

管制药品分级

我局曾告知贵公司，FDA拟建议根据《管制药品法案》(CSA) 对Orzeyful进行分级。截至本函发出之日，根据CSA (《美国法典》第21卷第811条) 对本品进行分级的工作尚未完成。因此，根据FDCA (《美国法典》第21卷第355(x)条)，Orzeyful的批准日期应为美国缉毒局 (DEA) 在《联邦公报》上发布公告，宣布oveporexton临时最终分级决定的日期。

我们注意到，当DEA对该药品进行分级后，贵公司需通过提交NDA补充申请的方式，对处方信息以及纸盒和容器标签进行适当修订。修订内容应包括根据《联邦法规汇编》第21篇第201.57(a)(2)和(c)(10)(i)条的要求，在药品说明书中加入声明，详细说明作为Orzeyful所含管制物质的oveporexton的分级情况。因此，只有在DEA于《联邦公报》发布公告宣布oveporexton的临时最终分级决定，且贵公司提交NDA补充申请以修订所有适用的药品说明书以反映该公告中所述的药品分级情况之后，Orzeyful方可上市销售。

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对于为说明Orzeyful的分级情况而对处方信息、纸盒和容器标签进行的变更，贵公司可提交《联邦法规汇编》第21篇第314.70(c)(6)条所述的"变更生效"补充申请。允许为此目的使用"变更生效"补充申请，是本局依据《联邦法规汇编》第21篇第314.90条，对《联邦法规汇编》第21篇第314.70(b)(2)(v)(C)条中规定的、为反映药品分级情况而对药品处方信息摘要进行变更时须提交"须经批准的补充申请"这一要求的豁免。

我们注意到，根据《美国法典》第21卷第355(x)条，Orzeyful将在批准之日被列入《橙皮书》。关于根据《联邦法规汇编》第21篇第314.53(c)(2)(ii)条要求提交专利信息事宜，我们注意到，贵公司必须在DEA于《联邦公报》发布公告宣

布oveporexton临时最终分级决定之日起30天内，提交FDA 3542表。

药品说明书内容

请尽快（但不迟于本函发出之日起14天内），按照FDA.gov网站上的说明¹，使用FDA自动化药品注册与列名系统（eLIST），以结构化产品标签（SPL）格式提交药品说明书内容[《联邦法规汇编》第21篇第314.50(l)条]。药品说明书内容必须与随附的药品说明书（处方信息）以及未包含在随附药品说明书中的、已在年度报告中报告的变更完全一致。

关于使用eLIST提交SPL文件的信息，可参见行业指南《SPL药品说明书内容标准技术问答》。²

SPL文件将通过公开的药品说明书信息库供公众查阅。

纸盒与容器标签

请在最终印刷的纸盒与容器标签可用后尽快提交，但不得晚于印刷后30天。提交的标签应与随附的纸盒与容器标签完全一致。请根据行业指南《SPL药品说明书内容标准技术问答》以电子方式提交这些标签。为便于管理，请将本次提交命名为“已批准的NDA 220860的最终印刷纸盒与容器标签”。在使用该标签前，无需获得FDA对本次提交的批准。

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

² 我们会定期更新指南。如需获取最新版本的指南，请查询FDA指南文件数据库

<https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>。

美国食品药品监督管理局

Silver Spring, MD 20993

www.fda.gov

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有效期

根据截至目前提交的稳定性数据，Orzeyful（oveporexton）片的有效期应为自生产之日起24个月，储存条件为20°C至25°C（68°F至77°F）；允许的温度偏移范围为15°C至30°C（59°F至86°F）（参见美国药典规定的室温控制条件）。

咨询委员会

贵公司关于Orzeyful的申请未提交至FDA咨询委员会进行讨论，因为对数据（用于治疗1型发作性睡病时）的评估未发现该类药物或在目标人群中存在重大或非预期的安全性或有效性问题。该申请未就该药品在疾病的诊断、治愈、缓解、治疗或预防中的作用提出重大的公共卫生问题。此外，也无需借助外部专业知识；总体而言，不存在可从咨询委员会讨论中获益的争议性问题。

要求的儿科评估

英文原文

NDA 220860

NDA APPROVAL

Takeda Pharmaceuticals USA, Inc.

Attention: Mark Swarz

Senior Director, Global Regulatory Affairs
500 Kendall Street
Cambridge, MA 02142

Dear Mark Swarz:

Please refer to your new drug application (NDA) received December 10, 2025, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Orzeyful (oveporexton) tablets.

This NDA provides for the use of Orzeyful (oveporexton) tablets for the treatment of narcolepsy type 1 (narcolepsy with cataplexy) in adult patients.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CONTROLLED SUBSTANCE SCHEDULING

You were previously informed that FDA intends to recommend scheduling of Orzeyful under the Controlled Substances Act (CSA). The scheduling of this product in accordance with the CSA (21 U.S.C. 811) is not yet complete as of the date of this letter. Therefore, in accordance with the FDCA (21 U.S.C. 355(x)), the date of approval for Orzeyful shall be the date on which the Drug Enforcement Administration (DEA) publishes a notice in the Federal Register announcing the interim final scheduling of oveporexton.

We note that, when the drug is scheduled by the DEA, you will need to make appropriate revisions to the Prescribing Information and carton and container labeling by submitting a supplement to your NDA. This would include the statements in the labeling detailing the scheduling of oveporexton, as the scheduled substance in Orzeyful, as required under 21 CFR 201.57(a)(2) and (c)(10)(i). Therefore, Orzeyful may be marketed only after DEA has published the notice in the Federal Register announcing the interim final scheduling of oveporexton and you submit a supplement to
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your NDA to revise all applicable drug labeling to reflect the drug scheduling described in the notice. For changes to the Prescribing Information, and carton and container labeling to describe the scheduling of Orzeyful, you can submit a Changes Being Effected supplement described in 21 CFR 314.70(c)(6). Permission to use a Changes Being Effected supplement for this purpose reflects a waiver by the Agency, pursuant to 21 CFR 314.90, of the requirement to submit a Prior Approval Supplement for changes to reflect the scheduling to the Highlights of Prescribing Information for DRUG PRODUCT described in 21 CFR 314.70(b)(2)(v)(C).

We note that Orzeyful will be listed in the Orange Book upon the date of approval in accordance with 21 U.S.C. 355(x). With respect to the submission of patent information, as required under 21 CFR 314.53(c)(2)(ii), we note that you must submit Form FDA 3542 within 30 days after the date on which DEA has published the notice in the Federal Register announcing the interim final scheduling of oveporexton .

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.

1 Content of labeling must be identical to the enclosed labeling (Prescribing Information) as well as annual reportable changes not included in the enclosed labeling. Information on submitting SPL files using eLIST may be found in guidance for industry SPL Standard for Content of Labeling Technical Qs and As.

2

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to guidance for industry, SPL Standard for Content of Labeling Technical Qs & As. For administrative purposes, designate this submission "Final Printed Carton and Container Labeling for approved NDA 220860." Approval of this submission by FDA is not required before the labeling is used.

1 <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

2 We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

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www.fda.gov

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DATING PERIOD

Based on the stability data submitted to date, the expiry dating period for Orzeyful (oveporexton) tablets shall be 24 months from the date of manufacture when stored at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) (see USP Controlled Room Temperature).

ADVISORY COMMITTEE

Your application for Orzeyful was not referred to an FDA advisory committee because the evaluation of the data (when used in the treatment of narcolepsy type 1) did not raise significant or unexpected safety or efficacy issues for a drug of this class or in the intended population. The application did not raise significant public health questions on the role of the drug in the diagnosis, cure, mitigation, treatment, or prevention of a disease. In addition, outside expertise was not necessary; overall, there were no controversial issues that would benefit from advisory committee discussion.

REQUIRED PEDIATRIC ASSESSMENTS

(原文因篇幅原因仅节选开头部分，完整全文请查阅上方FDA官方页面)

LUTETIUM LU 177 VIPIVOTIDE TETRAXETAN (PLUVICTO)

申请者/企业: NOVARTIS

日期: 2026-07-31

识别编号: NDA215833 (SUPPL-37)

FDA官方页面: <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=215833>

对中国企业的启示

诺华Pluvicto的适应症拓展,进一步验证了放射性配体疗法(RLT)作为前沿肿瘤治疗方向的临床价值与商业潜力。对布局该赛道的中国企业而言,这既确立了PSMA靶点的领先地位,也揭示了向更前线治疗拓展是关键的生命周期管理策略,提示后来者在制定出海策略时,需考虑在靶点、核素选择或适应症上实现差异化竞争。

中文翻译

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药品说明书内容

请在收到本函之日起 14 天内,尽快通过 FDA 自动化药品注册与列市系统 (eLIST),以结构化产品说明书 (SPL) 格式提交药品说明书内容 [21 CFR 314.50(l)],具体说明请见 FDA.gov。¹

药品说明书内容必须与随函附上的说明书(处方信息)完全一致,并包含任何待审的"已生效变更"(CBE) 补充申请中的说明书变更,以及未包含在随函附上说明书中的年度报告变更。

关于使用 eList 提交 SPL 文件的信息,可参见行业指南《药品说明书内容 SPL 标准技术问答》。²

SPL 将可通过公开的说明书存储库获取。

此外,请在 14 天内,使用 Microsoft Word 格式的药品说明书内容 [21 CFR 314.50(l)(1)(i)],修订本 NDA 所有包含说明书变更的待审补充申请,包括 FDA 尚未签发审评函的 CBE 补充申请。修订后的说明书内容应包含本次补充申请中批准的变更以及年度报告变更。为便于审评,请您在提交文件时,提供一份突出显示或标记所有变更的修订版,以及一份洁版 Microsoft Word 文档。标记版应提供适当的注释,包括补充申请编号和年度报告日期。

必需的儿科评估

根据《儿科研究公平法案》(PREA) (21 U.S.C. 355c),所有关于新活性成分(包括新盐和新固定组合)、新适应症、新剂型、新给药方案或新给药途径的申请,均需包含对该产品在儿科患者中用于所申请适应症的安全性和有效性评估,除非该要求被豁免、延期或不适用。

我们豁免本次申请的儿科研究要求,因为前列腺癌是一种成人相关疾病,在儿科人群中极为罕见,开展必要的研究是不可能或高度不切实际的。

1 <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

2 我们定期更新指南。如需获取最新版本的指南,请查询 FDA 指南文件数据库 <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>。

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需根据 506B 章节要求报告的上市后承诺

我们提醒您注意您的上市后承诺:

5034-1 完成正在进行的临床试验 PSMAddition (NCT04720157),题为"一项国际性、前瞻性、开放标签、随机、III 期研究,在转移性激素敏感性前列腺癌 (mHSPC) 成年男性患者中,比较 177Lu-PSMA-617

联合标准治疗与单独使用标准治疗",并提供预先计划的最终总生存期分析,以进一步表征 177Lu-PSMA-617

联合雄激素受体通路抑制剂 (ARPI) 治疗,用于前列腺特异性膜抗原 (PSMA) 阳性的转移性雄激素通路调节初治或敏感 (mAPMN/S) 前列腺癌成年患者的临床获益。

您在 2026 年 7 月 10 日提交的时间表表明,您将按照以下计划进行此项研究:

试验完成：2027 年 12 月

最终报告提交：2028 年 7 月

请随最终报告一并提交最终 OS 分析和数据集。

请将临床方案提交至您该产品的 IND 133661。请将非临床以及化学、生产和控制方案 and 所有上市后最终报告提交至本 NDA。此外，根据 21 CFR 314.81(b)(2)(vii) 和 314.81(b)(2)(viii) 的规定，您应在本 NDA 的年度报告中包含每项承诺的状态摘要。状态摘要应包括预计的摘要完成日期和最终报告提交日期、自上次年度报告以来的任何计划变更，以及（对于临床研究/试验）每项研究/试验的入组患者/受试者数量。所有与这些上市后承诺相关的递交材料，包括补充申请，均应显著标明"上市后承诺方案"、"上市后承诺最终报告"或"上市后承诺函件"。

推广材料

您可以就拟议的介绍性广告和推广说明书征求咨询意见。有关提交推广材料的信息，请参见行业指南《以电子和非电子格式提供监管递交材料--人用处方药的推广说明书和广告材料》。

您必须在首次分发或发布时提交最终推广材料和处方信息，并随附 FDA 2253 表格 [21 CFR 314.81(b)(3)(i)]。FDA 2253 表格可在 FDA.gov 获取。3 有关填写该表格的信息和说明可在 FDA.gov 找到。4

所有包含有关您药品产品陈述的推广材料，都必须立即修订，以与本补充申请中批准的说明书变更保持一致，包括任何新的安全性相关信息 [21 CFR 314.70(a)(4)]。您推广材料的修订内容应包括对……的显著披露

英文原文

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CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.

1 Content of labeling must be identical to the enclosed labeling (Prescribing Information) with the addition of any labeling changes in pending "Changes Being Effectuated" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in guidance for industry SPL Standard for Content of Labeling Technical Qs and As.

2

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which the FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a

highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for this application because necessary studies are impossible or highly impracticable to conduct on the basis that prostate cancer is an adult-related condition that rarely occurs in the pediatric population.

1 <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

2 We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

U.S. Food and Drug Administration

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POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitment:

5034-1 Complete the ongoing clinical trial, PSMAAddition (NCT04720157), titled "An International Prospective Open-label, Randomized, Phase III Study comparing 177Lu-PSMA-617 in combination with Standard of Care, versus Standard of Care alone, in adult male patients with Metastatic Hormone Sensitive Prostate Cancer (mHSPC)," and provide the pre-planned final overall survival analysis, to further characterize the clinical benefit of 177Lu-PSMA-617 in combination with androgen receptor pathway inhibitor (ARPI) therapy for adults with prostate-specific membrane antigen (PSMA)-positive metastatic androgen pathway modulation-naïve or-sensitive (mAPMN/S) prostate cancer.

The timetable you submitted on July 10, 2026, states that you will conduct this study according to the following schedule:

Trial Completion: 12/2027

Final Report Submission: 07/2028

Submit the final OS analysis and datasets with the final report submission.

Submit clinical protocols to your IND 133661 for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all postmarketing final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii) you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report

submission dates, any changes in plans since the last annual report, and, for clinical studies/trials, number of patients/subjects entered into each study/trial. All submissions, including supplements, relating to these postmarketing commitments should be prominently labeled "Postmarketing Commitment Protocol," "Postmarketing Commitment Final Report," or "Postmarketing Commitment Correspondence."

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see guidance for industry Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication

U.S. Food and Drug Administration

Silver Spring, MD 20993

www.fda.gov

Reference ID: 5845247

NDA 215833/S-037

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[21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.³ Information and Instructions for completing the form can be found at FDA.gov.⁴

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety- related information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the

(原文因篇幅原因仅节选开头部分，完整全文请查阅上方FDA官方页面)

SimpleScreen(TM) CRC

申请者/企业: Freenome, LLC

日期: 2026-07-24

识别编号: P250029

FDA官方页面: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P250029>

对中国企业的启示

Freenome结直肠癌血液筛查产品获FDA PMA批准，为中国肿瘤早筛企业提供了重要参照。该批准不仅在技术上验证了血液多组学路径的临床可行性与商业化潜力，更在监管层面为同类创新产品出海美国市场，清晰展示了所需遵循的严苛但可行的PMA审评路径与大规模前瞻性临床试验策略。这预示着全球竞争将围绕拥有高级别临床证据的产品展开。

相关资料

- 批准指令 (Approval Order): https://www.accessdata.fda.gov/cdrh_docs/pdf25/P250029A.pdf
- 安全性与有效性数据摘要 (SSED): https://www.accessdata.fda.gov/cdrh_docs/pdf25/P250029B.pdf
- 标签说明 (Labeling): https://www.accessdata.fda.gov/cdrh_docs/pdf25/P250029D.pdf

中文翻译

医疗器械: SimpleScreen(TM) CRC

通用名称: 结直肠肿瘤DNA甲基化及血红蛋白检测系统

申请人: Freenome, LLC Bldg. 1 3300 Marina Blvd. Brisbane, CA 94005

PMA编号: P250029

收到日期: 2025年8月1日

决定日期: 2026年7月24日

产品代码: PHP

案卷编号: 26M-8165

通知日期: 2026年7月24日

咨询委员会: 分子遗传学

临床试验: NCT04369053

是否授予加速审评?: 否

是否为组合产品?: 否

是否授权预定变更控制计划?: 否

摘要: 安全性和有效性摘要

标签: 标签第2部分

上市后研究: 显示报告计划和研究进展

批准令声明:

SimpleScreen(TM) CRC检测是一种定性体外诊断检测，旨在检测与结直肠癌相关的分子信号。SimpleScreen CRC利用从SimpleScreen CRC采血试剂盒采集的外周全血血浆中的循环游离DNA进行检测。SimpleScreen CRC适用于45岁及以上结直肠癌平均风险成人的筛查。检测结果为阳性的患者应进行结肠镜检查。SimpleScreen CRC不能替代诊断性结肠镜检查，也不能替代高风险人群的监测性结肠镜检查。

英文原文

Device: SimpleScreen(TM) CRC

Generic Name: System, colorectal neoplasia, DNA methylation and hemoglobin detection

Applicant: Freenome, LLC Bldg. 1 3300 Marina Blvd. Brisbane, CA 94005

PMA Number: P250029

Date Received: 08/01/2025

Decision Date: 07/24/2026

Product Code: PHP

Docket Number: 26M-8165

Notice Date: 07/24/2026

Advisory Committee: Molecular Genetics

Clinical Trials: NCT04369053

Expedited Review Granted?: No

Combination Product: No

Predetermined Change Control Plan Authorized: No

Summary: Summary of Safety and Effectiveness

Labeling: Labeling Part 2

Post-Approval Study: Show Report Schedule and Study Progress

Approval Order Statement:

The SimpleScreen(TM) CRC test is a qualitative, in vitro diagnostic test intended to detect molecular signals associated with colorectal cancer. SimpleScreen CRC utilizes circulating cell-free DNA from plasma of peripheral whole blood collected in the SimpleScreen CRC blood collection kit. SimpleScreen CRC is indicated for colorectal cancer screening in adults aged 45 years and older who are at average risk for the disease. Patients with a positive result should be followed by colonoscopy. SimpleScreen CRC is not a replacement for diagnostic colonoscopy or for surveillance colonoscopy in high-risk individuals.

HiResolution(TM) Bionic Ear System

申请者/企业: Advanced Bionics

日期: 2026-07-22

识别编号: P960058S167

FDA官方页面: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P960058>

对中国企业的启示

Advanced Bionics人工耳蜗系统进入PMA专家组审查，凸显了美国市场对有源植入式医疗器械极高的技术与临床准入门槛。这对于中国本土人工耳蜗企业而言，一方面明确了高端市场的技术迭代方向与竞争格局，另一方面也揭示其出海策略若想进入主流发达市场，必须在产品研发早期就规划并投入满足FDA等机构要求的、大规模且长期的临床证据链。

相关资料

- 批准指令 (Approval Order): https://www.accessdata.fda.gov/cdrh_docs/pdf/P960058S167A.pdf
- 安全性与有效性数据摘要 (SSED): https://www.accessdata.fda.gov/cdrh_docs/pdf/P960058S167B.pdf
- 标签说明 (Labeling): https://www.accessdata.fda.gov/cdrh_docs/pdf/P960058S167D.pdf

中文翻译

医疗器械: HiResolution(TM)仿生耳系统

通用名称: 人工耳蜗植入体

申请人: Advanced Bionics, 28515 Westinghouse Pl. Valencia, CA 91355

PMA编号: P960058

补充申请编号: S167

收到日期: 2025年1月29日

决定日期: 2026年7月22日

产品代码: MCM

专家咨询委员会: 耳鼻喉科

补充申请类型: 专家组审评通道

补充申请原因: 标签变更 - 适应证/说明/货架期/商品名

是否授予加速审评? 否

是否为组合产品? 否

是否授权预定变更控制计划? 否

摘要: 安全性和有效性摘要

标签: 标签第2部分

批准令声明:

单侧听力损失

HiResolution(TM)仿生耳系统适用于符合以下标准的单侧听力损失患者:

不对称性听力损失 (AHL)

AHL患者定义为: 较好耳为轻度至中重度听力损失, 即在500 Hz、1000 Hz、2000 Hz和4000

Hz的四频纯音听阈平均值 (4PTA) 为31至65 dB HL, 且双耳4PTA相差至少15 dB。建议AHL患者在进行人工耳蜗植入前, 至少有两 (2) 周佩戴经适当适配的对侧信号声路 (CROS) 系统或合适的助听设备的经验。待植入耳需满足以下条件:

成人 (18岁及以上): 重度至极重度感音神经性听力损失 (500、1000、2000和4000 Hz的4PTA $\geq$ 80 dB HL), 且在辅音-元音-辅音 (CNC) 单词测试中得分 $\leq$ 20%。

儿童 (5岁至17岁): 极重度感音神经性听力损失 (500、1000、2000和4000 Hz的4PTA $\geq$ 90 dB HL)。待植入耳在功能上无法充分获取声音, 其判定标准为: 单独测试待植入耳时, 在符合发育水平的单音节词表上的助听后言语感知测试得分 $\leq$ 5%。

单侧耳聋 (SSD)

SSD患者定义为: 较好耳听力正常或为轻度感音神经性听力损失 (500、1000、2000和4000 Hz的4PTA $\leq$ 30 dB HL)。建议SSD患者在进行人工耳蜗植入前, 至少有两 (2) 周佩戴经适当适配的对侧信号声路 (CROS) 系统或合适的助

听设备的经验。待植入耳需满足以下条件：

成人（18岁及以上）：重度至极重度感音神经性听力损失（500、1000、2000和4000 Hz的4PTA $\geq$ 80 dB HL），且在辅音-元音-辅音（CNC）单词测试中得分 $\leq$ 20%。

儿童（5岁至17岁）：极重度感音神经性听力损失（500、1000、2000和4000 Hz的4PTA $\geq$ 90 dB HL）。待植入耳在功能上无法充分获取声音，其判定标准为：单独测试待植入耳时，在符合发育水平的单音节词表上的助听后言语感知测试得分 $\leq$ 5%。

英文原文

Device: HiResolution(TM) Bionic Ear System

Generic Name: Implant, cochlear

Applicant: Advanced Bionics 28515 Westinghouse Pl. Valencia, CA 91355

PMA Number: P960058

Supplement Number: S167

Date Received: 01/29/2025

Decision Date: 07/22/2026

Product Code: MCM

Advisory Committee: Ear Nose & Throat

Supplement Type: Panel Track

Supplement Reason: Labeling Change - Indications/instructions/shelf life/tradename

Expedited Review Granted?: No

Combination Product: No

Predetermined Change Control Plan Authorized: No

Summary: Summary of Safety and Effectiveness

Labeling: Labeling Part 2

Approval Order Statement:

Unilateral Hearing Loss The HiResolution(TM) Bionic Ear System is indicated for individuals with unilateral hearing loss who meet the following criteria: Asymmetric Hearing Loss (AHL) Individuals with AHL are defined as those with a mild to moderately severe hearing loss in the better ear, i.e., a 4PTA of 31 to 65 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz, with a difference of at least 15 dB in the 4PTA between ears. It is recommended that individuals with AHL have at least two (2) weeks experience wearing an appropriately fitted Contralateral Routing of Signal (CROS) system or suitable hearing device prior to cochlear implantation. The ear to be implanted will be as follows: Adults (18 years of age or older): Severe to profound sensorineural hearing loss (4PTA of 500, 1000, 2000, and 4000 Hz = 80 dB HL) A score of = 20% on a Consonant-Nucleus-Consonant (CNC) word test Children (5 years through 17 years of age): Profound sensorineural hearing loss (4PTA of 500, 1000, 2000, and 4000 Hz = 90 dB HL) Insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of 5% or less on a developmentally appropriate monosyllabic word list when tested in the ear to be implanted alone. Single-Sided Deafness (SSD) Individuals with SSD are defined as those with normal hearing or mild sensorineural hearing loss in the better ear (4PTA of = 30 dB HL at 500, 1000, 2000, and 4000 Hz). It is recommended that individuals with SSD have at least two (2) weeks experience wearing an appropriately fitted Contralateral Routing of Signal (CROS) system or suitable hearing device prior to cochlear implantation. The ear to be implanted will be as follows: Adults (18 years of age or older): Severe to profound sensorineural hearing loss (4PTA of 500, 1000, 2000, and 4000 Hz = 80 dB HL) A score of = 20% on a Consonant-Nucleus-Consonant (CNC) word test Children (5 years through 17 years of age): Profound sensorineural hearing loss (4PTA of 500, 1000, 2000, and 4000 Hz = 90 dB HL) Insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of 5% or less on a developmentally appropriate monosyllabic word list when tested in the ear to be implanted alone.