

BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement (“Agreement”) is entered into as of this _____ day of _____, 20____ between _____, (“Covered Entity”) and Great Lakes Earmold Laboratory, Inc. (“Business Associate”).

RECITALS

WHEREAS, Business Associate provides hearing instruments and related services (“Services”) to or on behalf of Covered Entity;

WHEREAS, in the course of providing Services to or on behalf of Covered Entity, Business Associate will have access to Individually Identifiable Health Information, as hereinafter defined, maintained by Covered Entity that is protected as confidential under the Standards for privacy of Individually Identifiable Health Information promulgated pursuant to the Health Insurance portability and Accountability Act of 1996 as set forth at 45 CFR Parts 160 and 164 (the “Privacy Standards”); and

WHEREAS, Covered Entity is required by the Privacy Standards to enter into this Agreement and keep this Agreement in full force and effect in order to disclose and/or grant access to Individually Identifiable Health Information maintained by Covered Entity in connection with the performance of the Services; and

WHEREAS, this Agreement is intended to comply with the provisions of 45 CFR § 164.504(e).

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree as follows:

ARTICLE I. DEFINITIONS

1.1.1 1.1 **Individual**. “Individual” means the person who is the subject of Protected Health Information, as defined herein, and shall include a person who qualifies as a personal representative pursuant to 45 CFR § 164.502(g).

1.2 **Individually Identifiable Health Information**. “Individually Identifiable Health Information” is information, including demographic information collected from an individual, whether oral or recorded in any form or medium, that is:

- 1.2.1.1 created or received by a health care provider, health plan, employer or health care clearinghouse; and
- 1.2.2 relates to the past, present, or future health or condition, whether physical or mental, of and individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual; and
- 1.2.3 identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

1.3 Protected Health Information. “Protected Health Information” is Individually Identifiable Health Information that is maintained or transmitted in any form or medium.

1.4 Secretary. “Secretary” means the Secretary of the U.S. Department of Health and Human Services or his designee.

ARTICLE II.
OBLIGATIONS AND ACTIVITIES OF BUSINESS ASSOCIATE

2.1 Limitation on Use. Business Associate shall not use or further disclose Protected Health Information other than as permitted or required by this Agreement or as required by law or regulation. Any denial of an Amendment of Protected Health Information shall be the responsibility of the Covered Entity, including, but not limited to, resolution and/or reporting of all appeals and/or complaints arising there from

2.2 Appropriate Safeguards. Business Associate shall use appropriate safeguards to prevent use or disclosure of Protected Health Information other than as provided for by this Agreement.

2.3 Minimum Necessary. Business Associate represents and warrants that if it uses or discloses Protected Health Information, it shall do so only in the minimum amount and to the minimum number of individuals necessary to perform its obligations to or on behalf of Covered Entity.

2.4 Mitigation of Harm. Business Associate shall mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of Protected Health Information by Business Associate in violation of the requirements of this Agreement.

2.5 Report of Breach. Business Associate shall report to Covered Entity any use or disclosure of the Protected Health Information not provided for by this Agreement of which it becomes aware.

2.6 Agents/Subcontractors. Business Associate shall require that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by Business Associate on behalf of Covered Entity, agrees to essentially the same restrictions and conditions that apply through this Agreement to Business Associate with respect to such Protected Health Information.

2.7 Access to Books and Records. Business Associate shall make internal practices, books, and records, including policies and procedures and Protected Health Information, relating to the use and disclosure of Protected Health Information received from, or created or received by Business Associate on behalf of, Covered Entity available to the Secretary in a timely manner for purposes of the Secretary determining Covered Entity’s compliance with the Privacy Standards.

2.8 Documentation of Disclosures. Business Associate shall document disclosures of Protected Health Information and information related to such disclosures as would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information to the extent required by 45 CFR § 164.528.

2.9 Access to Information. Business Associate shall make Protected Health Information maintained in a Designated Record Set (as defined in the Privacy Standards) available to Covered Entity to fulfill its obligations in accordance with 45 CFR § 164.528.

2.10 Amendments. Business Associate shall incorporate any amendments to Protected Health Information maintained in a Designated Record Set that Covered Entity directs or to which it agrees to enable Covered Entity to fulfill its obligations in accordance with 45 CFR § 164.526.

2.11 Access to Protected Health Information. Business Associate agrees to make Protected Health Information available to an individual in accordance with 45 CFR § 164.524.

ARTICLE III.
PERMITTED USES AND DISCLOSURES
BY BUSINESS ASSOCIATE

3.1 Performance of Services. Except as otherwise limited in this Agreement, Business Associate may use or disclose Protected Health Information to perform the following functions, activities, or services for or on behalf of Covered Entity, provided that such use or disclosure would not violate the Privacy Standards if done by Covered Entity: Manufacture, Service, and Repair of Hearing Aids, Custom Earpieces, and Accessories.

3.2 Management and Administration. Except as otherwise limited in this Agreement, Business Associate may use or disclose Protected Health Information in providing Services under this Agreement as necessary for the proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate, provided that such use or disclosure would not violate the privacy standards if done by Covered Entity.

3.3 Compliance with Laws. Except as otherwise limited in this Agreement, Business Associate may use or disclose Protected health Information to report violations of law to appropriate Federal and State authorities or for any other purpose required by law, provided that such use or disclosure would not violate the Privacy Standards if done by Covered Entity.

ARTICLE IV.
OBLIGATIONS OF COVERED ENTITY

4.1 Disclosure. Covered Entity shall disclose Protected Health Information upon Business Associate's request or upon the request of a third party if such disclosure is permissible by law, so that Business Associate may provide services to or on behalf of Covered Entity, unless covered Entity otherwise objects to the disclosure, or Business Associate is no longer providing services to Covered Entity.

4.2 Notice of Privacy Practices. Covered Entity shall notify Business Associate of any limitations(s) in its notice of privacy practices of Covered Entity in accordance with 45 CFR § 164.520, to the extent that such limitation may affect Business Associate's use or disclosure of Protected Health Information.

4.3 Notice of Individual Revocations. Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by an Individual to use or disclose Protected Health Information, to the extent that such changes may affect Business Associate's use or disclosure of Protected Health Information.

4.4 Notice of Restrictions to Use. Covered Entity shall notify Business Associate of any restriction to the use or disclosure of Protected Health Information that covered Entity has agreed to in accordance with 45 CFR § 164.522, to the extent that such restriction may affect business Associate's use or disclosure of Protected Health Information.

4.5 No Impermissible Use. Covered Entity shall not request Business Associate to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Standards if done by Covered Entity.

ARTICLE V.
TERM AND TERMINATION

5.1 Term. This Agreement shall commence as of the date first above mentioned.

5.2 Termination. This Agreement shall terminate when all of the Protected Health Information provided by Covered Entity to Business Associate, or created or received by Business Associate on behalf of Covered Entity, is destroyed or returned to Covered Entity. If it is infeasible to return or destroy Protected health Information, Business Associate shall continue to extend the protections of this agreement to such information, in accordance with the termination provisions in Section 6.2.

5.3 Termination for Cause. Upon covered Entity's knowledge of a material breach by Business Associate of this Agreement, Covered Entity shall either:

- 5.3.1 provide an opportunity for Business Associate to cure the breach or end the violation and terminate this Agreement;
- 5.3.2 immediately terminate this Agreement if Business Associate has breached a material term of this Agreement and cure is not possible; or
- 5.3.3 if neither termination nor cure is feasible Covered Entity shall report the violation to the Secretary.

ARTICLE VI.
EFFECT OF TERMINATION

6.1 Return/Destruction of Information. Except as provided in Section 6.2 of this Agreement, and by regulations promulgated by (in) the Food and Drug Administration, upon termination of this Agreement, for any reason, Business Associate shall return or destroy all Protected Health Information received by Business Associate on behalf of Covered Entity. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies of the Protected Health Information.

6.2 Return/Destruction Infeasible. In the event that Business Associate determines that returning or destroying the Protected Health Information is infeasible, Business Associate shall provide to Covered Entity notification of the conditions that make return or destruction infeasible. Upon mutual agreement of the Parties that return or destruction of Protected Health Information is infeasible, Business Associate shall extend the protections of this Agreement to such Protected Health Information and limited further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such Protected Health Information.

6.3 Survival. The respective rights and obligations of Business Associate under Sections 6.1 and 6.2 of this Agreement will survive termination of this Agreement.

ARTICLE VII.
MISCELLANEOUS

7.1 Regulatory References. A reference in this Agreement to a section in the Privacy Standards means the section as in effect or as amended.

7.2 Amendment. The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the Privacy Standards.

7.3 Interpretation. Any ambiguity in this Agreement shall be resolved in favor of a meaning that permits Covered Entity to comply with the Privacy Standards.

7.4 Entire Agreement. This Agreement, as amended from time to time pursuant to Paragraph 7.2, constitutes the entire Agreement and understanding between the parties with respect to the Services specified and agreed upon in this Agreement and supersedes all prior oral or written agreements and understandings between them with respect to such services.

7.5 Severability. The invalidity of any portion of this document shall not invalidate the remainder, and the remainder shall continue in full force and effect.

7.6 Indemnification. Each party shall indemnify, hold harmless and defend the other party to this Agreement from and against any and all claims, losses, liabilities, costs, and other expenses incurred as a result or arising directly or indirectly out of or in connection with (a) any misrepresentation, breach of warranty or non-fulfillment of any undertaking on the part of the part under this Agreement; and (b) any claims, demands, awards, judgments, actions and proceedings made by any person or organization, arising out of or in any way connected with the party's performance under this Agreement.

7.7 Assignment. No party may assign or transfer any or all of its rights or obligations under this Agreement or any part of it, nor any benefit or interest in or under it, to any third party without the prior written consent of the other party which shall not be unreasonably withheld.

7.8 Notices. Any notice which may be or is required to be given under this Agreement shall be written and shall be sent by first class mail, fax, courier or as an electronic record attached to an e-mail. All notices shall be effective upon receipt at the addresses stated below which may be changed from time to time upon thirty (30) days' notice.

7.9 Headings. Headings are for convenience only and form no part of this Agreement and shall not affect its interpretation.

7.10 Governing Law. This Agreement shall be governed in accordance with the terms of any underlying agreement made between the parties wherein choice of law has already been negotiated and to which this Business Associate Agreement pertains, or in no previous choice of law provision exists, then in accordance with the substantive laws of the State of Incorporation of the Business Associate without regard to the conflicts of law principles.

IN WITNESS WHEREOF, the undersigned have executed this Agreement as of the day and year first written above.

Signature of Business Associate Representative Jessica Marx	Signature of Covered Entity Representative
Printed Name of Business Associate Representative 9/03/03	Printed Name of Covered Entity Rep
Date Great Lakes Earmold Laboratory, Inc.	Date
Company 750 Ken-Mar Industrial Parkway Cleveland, Ohio 44147-7930	Company
Address	Address

