Department of General Services

SOURCE JUSTIFICATION FORM

Bureau of Procurement

The objective of this form is to capture all relevant documentation an Agency may have to assist the Department of General Services ("DGS"), Bureau of Procurement, in expediting the source justification review process. This form must be completed electronically, signed, and submitted with all relevant documentation to DGS. If a question is neither mandatory nor applicable, please indicate "**N/A**". Please use standard terminology and define acronyms.

SECTION A

1. Agency Name:	Department of Health
2. Procurement Description: This description will appear on the eMarketplace website for public viewing	Two Otodynamics Otocheck ABR Screener Packages and related testing supplies; four Otodynamics Otocheck TEOAE Screener Standard Packages and related testing supplies; delivery of all equipment and supplies to the Department of Health, Harrisburg; and, onsite training at locations throughout Central, North East and South East Pennsylvania by an audiologist licensed to practice in Pennsylvania.
Materials Description:	Two Otodynamics Otocheck ABR Screener Packages. Each package includes: 1 Otodynamics Otocheck ABR Screener, 1 UGS TEOAE probe, 1 probe pouch, 1 probe cable clip, 1 TEOAE sample box of 125 tips, 1cc test cavity, 1 ABR test cavity, 1 electrode cable lead (1m), 1 electrode cable lead (2mm), 1 starter pack of AMBU electrodes, 1 tube of skin prep gel, cotton wool pads, 1 USB download cable, 1 infection control sleeve, 1 ABR desktop stand/crib hook, 1 compact wired Otoport charger, Otolink PC software and user documentation. Four Ambu Electrodes packs - pack of 25 (also includes one tube of NuPrep and one pack of cotton balls). Four Otodynamics Otocheck TEOAE Screener Standard Packages. Each package includes: 1 Otodynamics Otocheck TEOAE Screener, 1 probe; Otolink PC software; 1 download cable; manuals; 1 consumables starter pack (including box of probe tips); 1 charging cradle; 1 carry bag for both Otoport screener and standard accessories. 5 Otodynamics UGS TEOAE Probes (includes 5 replacement couplers, 5 replacement plastic probe bodies, 5 replacement plastic caps). 30 Spare Coupler Tubes packages for Transient Probes-(10 couplets per each package). 30 Transient Eartips 3mm-100/per package. 30 Transient Eartips 4.5mm-100/per package. 30 Transient Eartips 5.5mm-100/per package. 23 Infection Control Sleeve packages (10 sleeves in each package).
Services Description:	

3. Materials Shopping Cart # or Services SPR#	11904064	Estimated Cost:	$50,001 - $100K
		Initial Contract Term:	02/01/2016
		Renewals:	N/A

4. Supplier - Name:	E3 Diagnostics, DBA Midatlantic Technologies Group
Full Address:	3191 Trewigtown Road, Suite 100, Colmar, PA 18915-9731

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Contact Name:	Dr. Sherman Lord			
Telephone:	800-499-6844		FAX:	215-822-9732
E-mail:	slord@midlantictech.com			
SRM Supplier #:	407934			
5. Delivery or service location:	Department of Health, Bureau of Family Health, Div			

SECTION B

☐ **1. Sole Source:** Only known source - Not available from another supplier.

☑ **2. *Material/Repair/Maintenance*:** Material or service MUST be compatible with existing equipment. Documentation must be provided from the manufacturer.

☐ **3. *Used Equipment*:** Value set by 2 independent 3rd party appraisals.

☐ **4. *Professional Expert*:** Describe in detail in Section C.

☐ **5. Exempt (*Law*):** A federal or state statute or regulation exempts the procurement from the competitive procedure. Any applicable information precluding the procurement from competitive procedures must be attached.

☐ **6. Feasibility:** Clearly not feasible to award the contract on a competitive basis.

SECTION C

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1. Describe the unique features of this procurement that prohibit a competitive environment. If applicable, attach a Statement of Work ("SOW").	These newborn hearing screening units are medical devices used to test newborns and infants for hearing loss. The devices that are being purchased are the same type that the Department is currently using to screen out-of-hospital births throughout the commonwealth. The Department currently has 28 of these devices in service at locations throughout the commonwealth and two in inventory. The Department wishes to purchase the same devices that are currently being used since there are times the Department must replace or transfer the devices from one birthing/screening center to another. Using the same devices means the users within the screening network are familiar with the devices and don't require additional training when devices are replaced. Being able to quickly replace devices also allows newborns and infants to be screened timely without delay. Using the same devices also limits the types of testing medical supplies the Department must purchase and carry in inventory, helping to reduce program costs, and allows screeners to build quality screening practices that improve the screening outcomes. These devices can only be used to screen newborns and infants for hearing loss and should only be used to screen low birth populations. Hospitals with larger birth populations would not use this same type of equipment. This means that only a small number of these devises are sold.
2. Document and attach the research that has been conducted to date to verify the supplier is the only known source.	The medical devices are manufactured by Otodynamics Ltd. There are only two Pennsylvania authorized dealers (E3 Diagnostics, DBA Midatlantic Technologies Group; and, Gordon N. Stowe and Associates). Gordon N. Stowe and Associates, under agreement with Otodynamics Ltd, is only permitted to sell and support this equipment in a few counties (by zip code) in the extreme western part of PA. E3 Diagnostics, DBA Midatlantic Technologies Group is the only authorized dealer for the rest of the state (please see the attached additional information and letter from Otodynamics Ltd). These devices will only be located in Central, North East or South East Pennsylvania, the territory covered exclusively by E3 Diagnostics, DBA Midatlantic Technologies Group.

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3. Does the supplier utilize distributors, dealers, resellers, etc.? If "Yes," please identify.	These are medical devices manufactured by Otodynamics Ltd and sold only through authorized dealers. Due to extensive training, installation support, and warranty support issues included with each purchase, Otodynamics will not authorize the sale of the this product by distributors outside of the consumer's geographic support region. Violations of this agreement risk loss of on-site technical and warranty support. E3 Diagnostics, DBA Midatlantic Technologies Group is the sole and exclusive sales/service/support representative for Otodynamics Ltd. products in all counties of Pennsylvania with the exception of those counties directly on the western edge of the state sharing a border with Ohio (see attached Otodynamics letter and additional information).
4. Are there compatibility requirements or compliance requirements with a warranty or service agreement? If "Yes," please explain.	No
5. How has the material or service been procured in the past? Please provide previous source justifications, contracts, & PO's for this material or service.	In April 2015 four screening devices were purchased through sole source. Midlantic Technologies was the vendor. Purchase Order No: 4300443688.
6. If procured through the IT ITQ process, please provide original $ amount and contract period of order. Is this the final phase of the project?	N/A
7. If this is an upgrade, addition, alteration, etc., to an earlier procurement, please describe in detail.	N/A
8. What are the consequences of not approving this procurement?	These medical devices are used by free-standing birthing centers and midwives to test babies who were not born in a hospital for permanent childhood hearing loss. Without the devices, the babies will not be tested and hearing loss will not be timely identified. Late identification of hearing loss in newborns can negatively impact speech and language development, academic achievement and social-emotional development.
9. If timing is a factor, what is the time factor and why?	These devices are being purchased with federal grant funds and the purchase must take place on or before March 31, 2016.
10. List any other information relevant to the acquisition of this procurement here or as an attachment.	The equipment and supplies are to be delivered to Department of Health, Bureau of Family Health, 7th Floor East, Harrisburg, PA 17120. Department of Health staff will coordinate with E3 Diagnostics, DBA Midatlantic Technologies Group and the screening center a date and time for an onsite training by an audiologist from Midlantic. Department of Health staff will also attend the training.

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11. For requests > $100,000, has the supplier signed cost or pricing data certification and is the pricing breakdown attached?	N/A

SECTION D

IMPORTANT*: The printed names on this form shall constitute the signatures of these individuals. Agencies must insure that these individuals review the completed form and give their consent to apply their printed name on this form. No handwritten signatures shall be required in order for the form to be considered "signed" by those individuals whose names appear in the signature section of the form.

Shopping Cart Contact Person (Person whom DGS will contact regarding the Shopping Cart):

Name:	Tyler Ulrich	**P-Group:**	HA0	**Date:**	10-08-15
Title:	Central Office Purchaser	**Telephone:**		**Fax:**	

Agency Contact Person: Person in your agency that DGS can contact for additional information, etc.

Name:	Tyler Ulrich	**Title:**	Central Office Purchaser	**Date:**	10-08-15
Telephone:		**Fax:**		**Email:**	tyulrich@pa.gov

Approving Authority (Agency Head or Deputy reviewing and approving this request): Approving Authority connotes approval of the source justification and the cost or pricing data certification.

Name:	Lori Stubbs	**Title:**	Acting Director, Bureau of Adminis	**Date:**	11-18-15
Telephone:		**Fax:**			

Additional Approvals (if required by Agency):

Name:		**Title:**		**Date:**	
Telephone:		**Fax:**		**Email:**	
Name:		**Title:**		**Date:**	
Telephone:		**Fax:**		**Email:**	
Name:		**Title:**		**Date:**	
Telephone:		**Fax:**		**Email:**	
Name:		**Title:**		**Date:**	
Telephone:		**Fax:**		**Email:**	
Name:		**Title:**		**Date:**	
Telephone:		**Fax:**		**Email:**	
Name:		**Title:**		**Date:**	
Telephone:		**Fax:**		**Email:**	