THE DIVISION OF PROCUREMENT SERVICES
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Protest Decision

Matter of:	HemoCue America
Case No.:	2021-125
Posting Date:	February 23, 2021
Contracting Entity:	Department of Health and Environmental Control
Solicitation No.:	5400019915
Description:	Hemoglobin Analyzer Systems and Supplies

DIGEST

Protest that apparent successful bidder is not responsive is denied. The protest letter of HemoCue America (HCA) is included by reference. (Attachment 1)

AUTHORITY

The Chief Procurement Officer[1] (CPO) conducted an administrative review pursuant to S.C. Code Ann. §11-35-4210(4). This decision is based on materials in the procurement file and applicable law and precedents.

[1] The Materials Management Officer delegated the administrative review of this protest to the Chief Procurement Officer for Information Technology.

BACKGROUND

Solicitation Issued:	07/10/2020
Amendment 1 Issued	07/28/2020
Amendment 2 Issued	07/31/2020
Amendment 3 Issued	08/13/2020
Intent to Award Posted	01/11/2021
Intent to Protest Received	01/15/2021
Protest Received	01/25/2021

The South Carolina Department of Health and Environmental Control (DHEC) issued this Request for Proposals on July 10, 2020 to acquire hemoglobin analyzer systems and supplies. Amendment 1 was issued on July 28, 2020. Amendment 2 was issued on July 31, 2020. Amendment 3 was issued on August 13, 2020. Proposals were received on August 20, 2020. An Intent to Award to EKF Diagnostics, Inc. (EKF) was posted on January 11, 2021. HCA filed an Intent to Protest on January 15, 2021, followed by its formal protest on January 25, 2021.

ANALYSIS

HCA protests:

> The absence of information on the features of the EKF Analyzers and the failure to reference the EKF Analyzer in the 510K raises doubt on whether or not the EKF Analyzers fulfills the Solicitation specifications set forth in Sec 3.2.1 of the Solicitation.

Section 3.2.1 begins on page 17 of the solicitation and lists 13 requirements that the hemoglobin analyzer must meet. There is not a requirement that a description of the analyzer be accessible through the bidder's web site. HCA has the burden to prove the allegations it raises in its protest by a preponderance of the evidence. The absence of a description of the analyzer on the bidder's web site does not support an allegation that it does not meet the bid requirements.

HCA also suggests that the analyzer bid by EKF might not meet the specifications because the EKF's analyzer is not referenced by model number in the FDA's approval of 510(K) number K200909 issued to EKF on June 12, 2020. According to the FDA's web site, a 510(K) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device (section 513(i)(1)(A)

FD&C Act) that is not subject to premarket approval. (www.fda.gov) Documentation supporting the FDA approval includes a Summary and a Decision Summary. The Decision Summary states:

> This 510(k) submission contains information/data on modifications made to the submitter's own CLASS II device requiring 510(k). The following items are present and acceptable.
>
> 1. The name and 510(k) number of the SUBMITTER'S previously cleared device: Hemo_Control Hemoglobin Measurement System, K031898.

(emphasis added)

(https://www.accessdata.fda.gov/cdrh_docs/reviews/K200909.pdf, *lasted viewed* Feb. 22, 2021)

The Summary compares the K200909 approved device by model number 3040-0010-0218, with the K031898 approved device model number 3000-0031-6901 and concludes that they are substantially equivalent. HCA's allegation that the EKF analyzer is not referenced by model number in the 510K is not supported by the evidence, and even if it were, that omission would not support a finding that the analyzer does not meet the specifications listed in the solicitation.

The solicitation does require offerors to provide descriptive literature:

> 3.1.7. Descriptive Literature - Offerors are required to include with their offer the most current illustrated catalog data sheets with manufacturer's printed specifications covering the class or type of product(s) shown in the bid. The material should be sufficiently detailed to permit DHEC to properly evaluate the offer. The descriptive literature will be used for evaluation purposes.

EKF included four pieces of documentation related to the proposed analyzer:

> EKF_Hemo Control Analyzer Brochure
> EKF_Hemo Control Analyzer Data Management Brochure
> EKF_Hemo Control Analyzer Operators Manual
> EKF_Hemo Control Analyzer Operators Manual with Data Management

HCA has failed to meet its burden of proof and this issue of protest is denied.

HCA also suggests that the failure to reference the EKF analyzer by model number in the 510(K) suggests that the analyzer fails to meet the data management requirements of the solicitation:

> The data management functions necessary to meet the Solicitation specifications are at the core of the special 510K submission. The absence of information on the features of the EKF Analyzers and the failure to reference the EKF Analyzer in

> the 510K raises doubt on whether or not the EKF Analyzers fulfills the Solicitation specifications set forth in Sec 3.2.1 of the Solicitation.

The Decision Summary attached to the 510K also includes a description of the change to its previously cleared device:

> This change was for adding hardware functionality through connecting an external barcode scanner and software functionality through addition of a LIS2-A2 transfer protocol and optional data management functions. The additional hardware and software functionality enable users to add comments to results, request a quality control test and scan and record the information including operator identification, cuvette lot information, patient identification and laboratory identification.

(https://www.accessdata.fda.gov/cdrh_docs/reviews/K200909.pdf, *lasted viewed* Feb. 22, 2021)

As stated above, EKF provided a data management brochure and operators manual with its proposal for evaluation. HCA has failed to meet its burden of proof, and this issue of protest is denied.

HCA next alleges:

> Further we suspect that the EKF Analyzers do not include a docking station which is a requirement set forth in the Solicitation (See Sec. 3.2.3.1 of the Solicitation).

The solicitation provides:

> 3.2.3. Hb 201 DM shall have data self-storage and data management capability.
> 3.2.3.1. Shall have compatible docking station ability.
> 3.2.3.2. Shall have printing software capability.

[Solicitation, Page 18]

The solicitation provides:

> DHEC currently utilizes HemoCue Hemoglobin Analyzer Systems Hb 201+, Hb 201 DM, HemoCue Microcuvettes, and R&D Glu/Hgb Tri-Level Controls for its Family Planning and Women, Infant and Children (WIC) regional clinics….
>
> Any manufacturer's names, trade names, brand names, or catalogue numbers used in the specifications are for the purpose of describing and establishing general performance and quality levels. Such references are not intended to be restrictive. Proposals are invited on these and comparable brands or products provided the quality of the proposed products meet or exceed the quality of the specifications listed for any item.
>
> DHEC will consider other products that meet or exceed the brand name specifications designated as "or equal" on the bidding schedule. (emphasis added)

[Solicitation, Page 17]

Item 3 in the Bidding Schedule requested pricing for a:

> 121135 - HB201 DM Analyzer
> HemoCue brand, or DHEC approved equivalent

Item 4 in the Bidding Schedule requested pricing for

> 139143 - HB201 DM Primary Docking Station

For both items, the bidding schedule provided:

> If you are bidding an equal, you must state the BRAND you are bidding and the manufacturer's item number. You must also include the manufacturer's descriptive literature.

In response to item 3, EKF Diagnostic indicated that it is offering an equal product as follows:

> Item #3040-0010-0218 = Hemo Control Analyzer + 3040-7201-0099 = DM Add Pack;3000-7052-0028 = USB cable for Hemo Control. Literature attached.

In response to item 4 EKF Diagnostic responded:

> "The Hemo Control Analyzer does not require a docking station to operate with the DM add pack."

In response to this issue of protest, DHEC responds:

> DHEC Lowcountry Region clinics are the only users of the 40 existing HB201 DM Analyzers. The 3 other DHEC Regions use the existing 138 hand-held/counter top HB201+ Analyzers (provided by the current vendor HemoCue, that do not have a docking station). After evaluation, it was determined that the proposal by EKF had compatible docking station ability and their product was deemed an approved equivalent.

EKF bid an acceptable equivalent product. This issue of protest is denied.

Finally, HCA alleges:

> Not only is the requirement for a docking stating clearly established but it is also it's own separate item in Section VIII Bidding Schedule/ Price-Business Proposal of the Solicitation. Each separate item in this section has questions and answers. For each question, it is assigned to be either "Mandatory" or "Optional". All related questions to this specific item (Line Number 004) are marked as Mandatory by the state. We are aware that a "DHEC approved equivalent" could be considered, but nowhere is it stated in the Solicitation that a Mandatory and

separate Item (Line Number 004) can be omitted from the products sought under the Solicitation.

DHEC provides the following response:

HemoCue misunderstands the purpose and scope of the Mandatory Questions in the Bidding Schedule. Below are the Mandatory questions in the Bidding Schedule related to item 4 and EKF's response.

Line Number	Quantity	Unit of Measure	Unit Price	Extended Price
0004	1	each	$0.00	
Product Catalog: 19312 - Blood Chemistry & Hematology Reagents & Supplies				
Item Description: **139143 - HB201 DM PRIMARY DOCKING STN**				
Tendering Text: HemoCue brand, or DHEC approved equivalent.				
Question		**Mandatory / Optional**	**Multiple Responses Accepted?**	**Response**
The bidder has read and understands all Amendments.		Mandatory	No	__X__ Yes _____ No
1. The Submitter has read and understands the terms and conditions of this solicitation.		Mandatory	No	__X__ Yes. I have read and understand the terms and conditions.
2. The offer is in accordance with the terms and conditions of this solicitation.		Mandatory	No	__X__ Yes, I am in accordance with the terms and conditions.
If you are bidding an equal, you must state the BRAND you are bidding and the manufacturer's item number. You must also include the manufacturer's descriptive literature.		Mandatory	No	The Hemo Control Analyzer does not require a docking station to operate with the DM add pack.

HemoCue misinterpreted the mandatory questions in the bidding schedule as a requirement of the specifications. These mandatory bidding questions are not directly related to the specifications. What is mandatory is for the bidder to respond to the questions in the bidding schedule. EKF did provide a response to these mandatory questions in their proposal.

This issue of protest is dismissed.

DECISION

For the reasons stated above, the protest by HemoCue America. is denied.

For the Materials Management Office

Michael B. Spicer
Chief Procurement Officer

Attachment 1

From: Bellwood, Mark C
To: Protest-MMO
Subject: [External] Solicitation 5400019915 (protest detail)
Date: Monday, January 25, 2021 6:49:15 PM

A Hard copy has also been mailed out.

CONTAINS CONFIDENTIAL AND PROPRIETARY INFORMATION WHICH MAY NOT BE RELEASED WITHOUT THE PRIOR WRITTEN PERMISSION OF HEMOCUE AMERICA

January 25, 2021
Chief Procurement Officer
Materials Management Office
1201 Main St. Suite 600
Columbia, SC 29201

RE: Solicitation 5400019915 ("Solicitation")

To the Chief Procurement Officer,
Per the requirement established in Section 11-35-4210(1)(b), this letter sets forth the grounds of HemoCue America's ("HCAM") protest of the Solicitation and seeks the relief requested .
The Intent to Award for the Solicitation selects EKF Diagnostics ("EKF") as the vendor to provide the products specified in the Solicitation, and specifically mentions EKF's Hemo Control Analyzer (part) #3040-0010-0218 ("EKF Analyzer"). For the reasons we outline below, the EKF Analyzer fails to meet the requirements of the Solicitation and as such HCAM should be selected as the vendor for the products at issue in the Solicitation.

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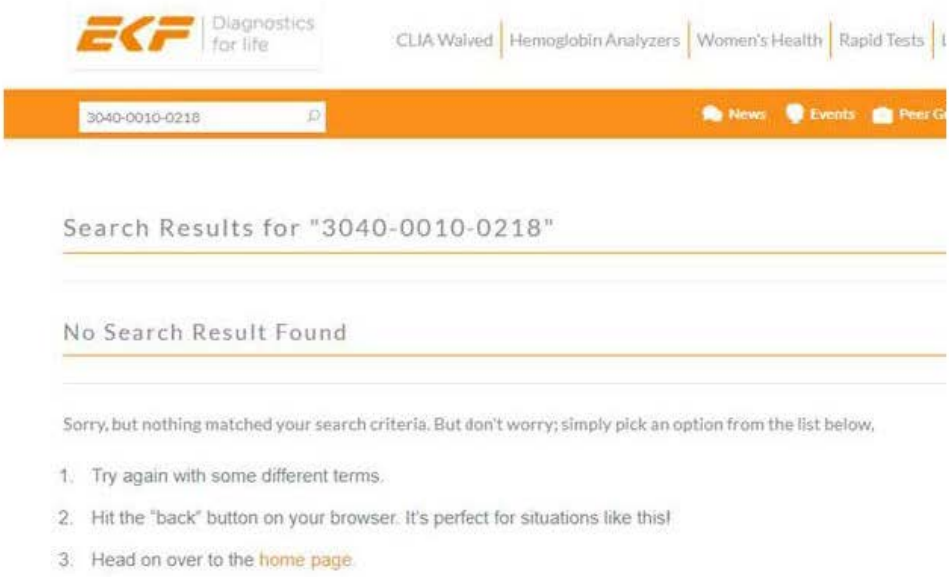
EKF Analyzers fail to meet the Solicitation's requirements

A search for the EKF Analyzer on EKF's website returns no results, either by number or name. See the screenshot below from the site [ADDRESS] visited on DATE



Upon further investigation, it seems that a Special 510k was received by EKF 20 business days before the issuance of this Solicitation. See the screenshot from the FDA's website at |ADDRESS| visited on DATE

New Search | Export to Excel | Download Files | More About 510(k)

Device Name	Applicant	510(K) Number	Decision Date
Hemo Control (Optional Add Pack Hemo Control Dm)	EKF-Diagnostic GmbH	K200909	06/12/2020
Ekf Diagnostic Hemo control Hemoglobin Measurement System; Ekf-Diagnostic Hemoglobin Microcuvettes (Modified Curvette W	EKF-DIAGNOSTIC GMBH	K110393	03/04/2011
Ekf Diagnostic Hemo Control Hemoglobin Measurement System	EKF DIAGNOSTIC GMBH	K031898	09/24/2003

The Special 510K issued does not reference the EKF Analyzer (part number 3040-0010-0218) indicating that the EKF Analyzer does not contain the features mentioned in the special 510K. When looking deeper at the Special 510K, the decision summary states (attached):

This change was for adding hardware functionality through connecting an external barcode scanner and software functionality through addition of a LIS2-A2 transfer protocol and optional data management functions. The additional hardware and software functionality enable users to add comments to results, request a quality control test and scan and record the information including operator identification, cuvette lot information, patient identification and laboratory identification.

The data management functions necessary to meet the Solicitation specifications are at the core of the special 510K submission. The absence of information on the features of the EKF Analyzers and the failure to reference the EKF Analyzer in the 510K raises doubt on whether or not the EKF

Analyzers fulfills the Solicitation specifications set forth in Sec 3.2.1 of the Solicitation.
Further we suspect that the EKF Analyzers do not include a docking station which is a requirement set forth in the Solicitation (See Sec. 3.2.3.1 of the Solicitation).
Not only is the requirement for a docking stating clearly established but it is also it's own separate item in Section VIII Bidding Schedule/ Price-Business Proposal of the Solicitation. Each separate item in this section has questions and answers. For each question, it is assigned to be either "Mandatory" or "Optional". All related questions to this specific item (Line Number 004) are marked as Mandatory by the state. We are aware that a "DHEC approved equivalent" could be considered, but nowhere is it stated in the Solicitation that a Mandatory and separate Item (Line Number 004) can be omitted from the products sought under the Solicitation.

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HCAM Analyzers are able to meet the Solicitation's requirements

There is more than one function performed by the HemoCue HB201 DM Primary Docking Station. Beyond simply being the conduit for the bilateral communication function, the primary docking station also:

-enables connection of up to 5 analyzers
-provides a safe, hard-wired ethernet connection
-indicates to the state if each analyzer is docked, functioning properly and has received/sent all information either downloaded or uploaded.
-fully charges the analyzer for participant/patient use

I have attached the operator's manual for HCAM's Hb201 DM System which goes into great detail on all of the unique features of the primary docking station and to show the clear superiority of our analyzers compared to the EKF Analyzer.

Conclusion and Relief Sought

In summary we do not believe that the Intent to Award to EKF is valid. There is no publicly available information on the features of the EKF Analyzer to show that it meets the requirements of the Solicitation. Also, if the EKF Analyzer has no docking station, it is our belief that the EKF Analyzer does not meet the established clear criteria for a docking station set forth in the Solicitation. If that is the case, such analyzer should not be considered as equivalent and should be disqualified and the award should be made to HCAM.

Sincerely,

Mark Bellwood

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www.hemocue.us

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STATEMENT OF RIGHT TO FURTHER ADMINISTRATIVE REVIEW

Protest Appeal Notice (Revised May 2020)

The South Carolina Procurement Code, in Section 11-35-4210, subsection 6, states:

> (6) Finality of Decision. A decision pursuant to subsection (4) is final and conclusive, unless fraudulent or unless a person adversely affected by the decision requests a further administrative review by the Procurement Review Panel pursuant to Section 11-35-4410(1) within ten days of posting of the decision in accordance with subsection (5). The request for review must be directed to the appropriate chief procurement officer, who shall forward the request to the panel or to the Procurement Review Panel, and must be in writing, setting forth the reasons for disagreement with the decision of the appropriate chief procurement officer. The person also may request a hearing before the Procurement Review Panel. The appropriate chief procurement officer and an affected governmental body shall have the opportunity to participate fully in a later review or appeal, administrative or judicial.

Copies of the Panel's decisions and other additional information regarding the protest process is available on the internet at the following web site: http://procurement.sc.gov

FILING FEE: Pursuant to Proviso 111.1 of the 2020 General Appropriations Act, "[r]equests for administrative review before the South Carolina Procurement Review Panel shall be accompanied by a filing fee of two hundred and fifty dollars ($250.00), payable to the SC Procurement Review Panel. The panel is authorized to charge the party requesting an administrative review under the South Carolina Code Sections 11-35-4210(6), 11-35-4220(5), 11-35-4230(6) and/or 11-35-4410…Withdrawal of an appeal will result in the filing fee being forfeited to the panel. If a party desiring to file an appeal is unable to pay the filing fee because of financial hardship, the party shall submit a completed Request for Filing Fee Waiver form at the same time the request for review is filed. *[The Request for Filing Fee Waiver form is attached to this Decision.]* If the filing fee is not waived, the party must pay the filing fee within fifteen days of the date of receipt of the order denying waiver of the filing fee. Requests for administrative review will not be accepted unless accompanied by the filing fee or a completed Request for Filing Fee Waiver form at the time of filing." PLEASE MAKE YOUR CHECK PAYABLE TO THE "SC PROCUREMENT REVIEW PANEL."

LEGAL REPRESENTATION: In order to prosecute an appeal before the Panel, business entities organized and registered as corporations, limited liability companies, and limited partnerships must be represented by a lawyer. Failure to obtain counsel will result in dismissal of your appeal. *Protest of Lighting Services*, Case No. 2002-10 (Proc. Rev. Panel Nov. 6, 2002) and *Protest of The Kardon Corporation*, Case No. 2002-13 (Proc. Rev. Panel Jan. 31, 2003); and *Protest of PC&C Enterprises, LLC*, Case No. 2012-1 (Proc. Rev. Panel April 2, 2012). However, individuals and those operating as an individual doing business under a trade name may proceed without counsel, if desired.

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~~*Protest Appeal Notice (Revised June 2019)*~~

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South Carolina Procurement Review Panel
Request for Filing Fee Waiver
1205 Pendleton Street, Suite 367, Columbia, SC 29201

_____ _____

Name of Requestor Address

_____ _____

City State Zip Business Phone

---

1. What is your/your company's monthly income? _____

2. What are your/your company's monthly expenses? _____

3. List any other circumstances which you think affect your/your company's ability to pay the filing fee:

_____

_____

_____

To the best of my knowledge, the information above is true and accurate. I have made no attempt to misrepresent my/my company's financial condition. I hereby request that the filing fee for requesting administrative review be waived.

Sworn to before me this
_____ day of _____, 20_____

_____ _____

Notary Public of South Carolina Requestor/Appellant

My Commission expires: _____

For official use only: _____ Fee Waived _____ Waiver Denied

_____

Chairman or Vice Chairman, SC Procurement Review Panel

This _____ day of _____, 20_____
Columbia, South Carolina

NOTE: If your filing fee request is denied, you will be expected to pay the filing fee within fifteen (15) days of the date of receipt of the order denying the waiver.