Ref. No.08/Stores (DO)/Pead/Proprietary/2013-14/FSC

Dated: 5th July 2013

Subject: Purchase of **WBC Analyzer** for the department of Pediatrics at AIIMS, New Delhi-29 on proprietary basis - **Inviting comments thereon.**

*****

The Institute is in the process to purchase **WBC Analyzer** for the department of Pediatrics at AIIMS, New Delhi-29 from M/s.HemoCue AB, Sweden on proprietary basis. The proposal submitted by M/s.DeAsh Trade-net Pvt. Ltd. New Delhi-01 (Authorized Indian Agent) and PAC certifications are attached.

The above documents are being uploaded for open information to submit objections, comments, if any, from any manufacturer regarding proprietary nature of the equipment/item within issue of 15 days giving reference No.08/Stores(Do)/Pead/Proprietary/2013-14/FSC. The comments should be received by office of Stores Officer (DO), Store Section, Animal House Building, Near Biotechnology Building at AIIMS on or before **25.07.2013 upto 12.30 p.m.,** failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

Yours faithfully,

STORES OFFICER (DO)

Encl: Related documents enclosed.
**PERFORMA INVOICE**

F - 51, Kishangarh Road, Kamla Nagar
New Delhi - 110071 Ph : 011-23038138

Customer Address: HOD Department of Paed
All India Inst. Of Medical Sciences
New Delhi

**Tender No:**
**Due On:**
**Tender for:** HemoCue B

<table>
<thead>
<tr>
<th>ITEM</th>
<th>QTY</th>
<th>DESCRIPTION</th>
<th>UNIT PRICE (INR)</th>
<th>DISCOUNTED PRICE (INR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC</td>
<td>1</td>
<td>HemoCue WBC Microcuvette 4 Bottles of 40 Tests each. Total of 160 Tests <strong>In words : Rs Twenty seven thousand two hundred only</strong></td>
<td>34,000.00</td>
<td>26,200.00</td>
</tr>
<tr>
<td>WBC</td>
<td>1</td>
<td>HemoCue WBC Analyzer <strong>As desired &amp; negotiated, we'll provide two boxes of Microcuvette &quot;FREE OF COST &quot; along with the Analyzer.</strong></td>
<td>125,000.00</td>
<td>85,000.00</td>
</tr>
</tbody>
</table>

**TOTAL RS.** 111,200.00
**ADD VAT @ 5%** 5,560.00
**G. TOTAL** 116,760.00

**Terms & Conditions:**
1. Delivery: 4 - 6 weeks from confirmed PO
2. Payment: 100% on delivery
3. Warranty: One year from the date of PO

(In words: Rs. One lac sixteen thousand seven hundred sixty only)

Accepted this proposal

For DeAsh Trade-Net Pvt Ltd

Authorized Signatory

---

DeAsh Trade-Net Private Limited
Regd. Office: 7th Floor, Kishangarh Road, Kamla Nagar. New Delhi - 110071; Ph : 011-23038138
Branch Office: LBR 14B & E, Anurag Building, 10, Bapuji Enclave, New Delhi - 110020; Tel : 011-4374455
Branch Office: Level 2, 104, Goalam Bhawan, Hotel Mahadevi Plaza Complex, N.I.T., Faridabad-121001
Ph : +91-129-930290, 2643278; Fax : +91-129-2643278; e-mail : chem-rashmi@rediffmail.com
Specifications WBC Analyzer

- Method: The white blood cell count should be determined by hemolyzation of red cells and color staining of white cells in the WBC microcuvette. An image should be taken of the stained white cells and the number of cells should be counted in the WBC analyzer.
- Calibration: System should be Factory calibrated and need no further calibration.
- System should comply with IVD Medical Device Directive 98/79/EC.
- Power Saver Mode: If the analyser is operating on battery power, but not being used, it should automatically turn off after approximately five minutes and if operating on AC power, it should turn off after approximately 2 hours.
- Weight: 600 g with batteries installed.
- Measuring Range: 0.3-30.0x10\(^9\)/L (300-30000/mm\(^3\)).
- Dimensions: 185x133x120 mm.
- Analyzer should be tested for electrical safety and EMC according to EN 61010-2-101:2002 Safety requirements for electrical equipment for measurement, control and laboratory use- Part 2-101: Particular requirement for IVD medical equipment.
- Manufacturer should have ISO 9001:2008 certification.
- Analyzer should be CE/USFDA Certified.
- Validation in clinical Laboratory: \(r_2 = 0.995\) compared with Cell Counter.
- Measuring Time: 3 minutes.
- Sample Material: Capillary or Venous (EDTA) whole blood.
- Sample Volume: 10\(\mu\)L.
- Interfaces: RS 232 (Printer).
- Quality Control: Built – in self test.
- Operating Temperature: 15-35\(^\circ\)C.
- Storage Temp: Cuvettes: 15-35 \(^\circ\)C, Analyser: 0-50 \(^\circ\)C.
- Power: 6AA (1.5 V) Batteries or Power adapter.

*****
A sample acquiring device for volumetric enumeration of white blood cells in a blood sample that includes a measurement cavity for receiving a blood sample. The measurement cavity has a predetermined fixed thickness. The sample acquiring device also has a reagent, which is arranged in a dried form on a surface defining the measurement cavity. The reagent has a hemolyzing agent for lysing red blood cells in the sample and a staining agent for selectively staining white blood cells in the sample. Also, a system with the sample acquiring device and a measurement apparatus. The measurement apparatus has a sample acquiring device holder, a light source, and an imaging system for acquiring a digital image of a magnification of the sample. The measurement apparatus also has an image analyzer arranged to analyze the acquired digital image for determining the number of white blood cells in the blood sample.
5.0 510(k) Summary
Submitter: HemoCue AB
Box 1204
Angelholm, Sweden SE-262 23
+46 431 45 82 00 (Telephone)
+46 431 45 8225 (FAX)
Contact: Mr. Allan White (Official Correspondent)
HemoCue, Inc.
40 Empire Drive
Lake Forest, CA 92630-2244
(949) 859-2630 x10 (Telephone)
(949) 598-8630 (FAX)
allan@hemocue.com
Date of Preparation: June 14, 2007
Common name of device: Semi-Automated Cell Counter
Proprietary Name: HemoCue WBC System
Class: Class II
Panel: Hematology (81)
Regulation number: Automated and Semi-Automated Hematology Devices,
21 CFR § 864.5200 Automated Cell Counter or Semi-Automated Cell Counter
Product Code: GKL
Equivalent to: HemoCue AB claims substantial equivalence to the current
legally marketed device: Sysmex XS-1100i, Automated
haematology analyzer (1K060656) and Manual light
microscopic WBC method (class I exempt)

5.1 Device Description
The system consists of the HemoCue WBC Analyzer together with specially designed
microcuvettes, the HemoCue WBC Microcuvettes. The microcuvette serves both as a
sample container and a reaction chamber. A blood sample of approximately 10 µl, is
drawn into the cavity by capillary action. A hemolyzing agent lyses the red cells in the
microcuvette and a staining agent colors the white blood cells. An image is taken of the
stained white blood cells and the number of cells is counted by image analysis. The
result is presented within 3 minutes on the analyzer's display. The system reports results
in the measuring range 0.3 -30.0 x10^9 L. The system is factory calibrated and needs no
further calibration.

5.2 Indications for Use
The HemoCue WBC system is indicated for use for quantitative determination of white
blood cell (WBC) count in capillary or venous whole blood. The HemoCue WBC
system is for In Vitro Diagnostic use only. The HemoCue WBC Analyzer is only to be
used with HemoCue WBC Microcuvettes. The HemoCue WBC system is indicated for
use in clinical laboratories and for point-of-care settings.

5.3 Summary of Technological Characteristics
The HemoCue WBC Analyzer
The HemoCue WBC Analyzer (figure 1) is a portable device. The main parts are the
cuvette holder (in which the microcuvette is placed), the cuvette moving arm (brings the
microcuvette into correct measuring position), a magnifying optic unit, a camera, image
processing software, a display and a power adapter.
The HemoCue WBC Microcuvette

The HemoCue WBC Microcuvette (Figure 2) is made of polystyrene plastic and contains saponin that hemolyzes the red blood cells, methylene blue that stains the white blood cells and nonactive reagents. A blood sample of approximately 10 gL is drawn into the cavity by capillary action. The microcuvette serves as a sample container and a reaction chamber. No dilution of the sample is required.

Figure 2. The HemoCue WBC Microcuvette

5.4 Similarities and Differences with Predicate Devices

The HemoCue WBC system is a semi-automated device intended for use for the quantification of White Blood Cells in clinical laboratories and point of care settings. The Sysmex XS 1000i (predicate device) is an automated hematology analyzer for use in clinical laboratories.

Light microscopes (predicate device) are used as to enumerate leukocytes in a haemocytometer mounted on the stage of the microscope and read manually.

Similarities and Differences: All three devices quantify leucocytes (WBCs), but the Sysmex XS device also quantifies red blood cells, platelets, hemoglobin, hematocrit and provides a differential cell count.

5.5 Assessment of Performance

Studies were conducted in-house, in clinical laboratory settings and point of care settings to demonstrate the performance with intended specifications of the HemoCue WBC system and to validate that the intended user can easily operate the system and obtain results as expected.

5.6 Conclusion

Based on the information and performance data presented in this premarket notification, the HemoCue WBC system meets the manufacturer's intended use specifications and is substantially equivalent to the Sysmex XS-system and the manual light microscopic method of counting WBC.
devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).
You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474.
For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industrv/support/index.html.
Sincerely yours,
RDLoirb~cr to r Bek
Division of Immunology and Hematology
Office of In Vitro Diagnostic Device Evaluation
and Safety
Center for Devices and Radiological Health
Enclosure

**4.0 Statement of Indications of Use**

510(k) Number: K 02 / G 9

Device Name: HemoCue® WBC system

Indications For Use:
The HemoCue WBC system is indicated for use for quantitative determination of white blood cell (WBC) count in capillary or venous whole blood. The HemoCue WBC system is for In Vitro Diagnostic use only. The HemoCue WBC Analyzer is only to be used with HemoCue WBC Microcuvettes. The HemoCue WBC system is indicated for use in clinical laboratories and for point-of-care settings.

Prescription Use X Over-The-Counter Use

(Part 21 CFR 801 Subpart D) AND/OR (21 CFR 801 Subpart C)

(Please do not write below this line. Continue on another page if needed)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Div/ Ofce of In Vtro Diagnostic Device

Evaluation and Safety

5 1 0(k) 4K O 4:

HemoCue WBC system Section 4 4:1

*****