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CLASS JUSTIFICATION FOR AN EXCEPTION TO FAIR OPPORTUNITY (JEFO)
SUCTION ASPIRATOR
CORPORATE EXIGENCY CONTRACT SPE2D1-24-D-0018

(1) Defense Logistics Agency (DLA) Troop Support, Medical Supply Chain, Capital Equipment Division, is the contracting activity.

(2) The action submitted for approval is a class JEFO for the placement of sole source delivery orders for Zoll 330M Suction Aspirators National Stock Number (NSN): 6515-01-672-4118 United States Air Force (USAF) configuration and NSN 6515-01-677-5151 United States Army (US Army) configuration), related accessories, and repair/replacement parts under Zoll Medical's Corporate Exigency Contract (CEC) SPE2D1-24-D-0018, for the period commencing with the approval of this class JEFO through contract expiration on September 24, 2029.

(3) The USAF and the US Army have ongoing requirements for Zoll 330M Suction Aspirators, related accessories, and repair/replacement parts. The total maximum dollar value of Zoll Medical's above referenced CEC is $49.2 million. This contract was awarded on September 25, 2024. Based on the estimated forecasted demand from the USAF and the US Army for Zoll 330M Suction Aspirators through September 2029, the forecasted dollar value of the sole source delivery orders to be placed under the referenced five (5) year contract is [redacted]

(4) The authority waiving the competition requirements is FAR16.505 (b)(2)(i)(B): only one (1) source is capable of providing the supplies or services required at the level of quality required because the supplies or services ordered are unique or highly specialized.

The USAF and the US Army requires the Zoll 330M Suction Aspirators to replace previous generation Zoll Suction Aspirators, which are about to reach end-of-service life over the next five (5) years. The newer Zoll 330M Suction Aspirator will support the US Army Field Hospitals, and the USAF medical Patient Movement Item (PMI) Centers, Aeromedical Evacuation (AE) Inflight Kits, Critical Care Air Transport Teams (CCATT), Tactical Critical Care Evacuation Team (TCCET), Small Aircraft Kits (C21), and Ground Medical Assemblages, as did its predecessor. The required Suction Aspirators will cross the entire continuum of care in both Services' deployable medical systems.

The Suction Aspirator must meet the following minimum requirements which were developed, reviewed, edited, and approved by U.S. Army Medical Material Development

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Activity (USAMMDA), Air Mobility Command/Command Surgeon's Office (AMC/SGXM) appointed Subject Matter Experts (SMEs) and USAF Surgeon General SMEs:

a. Device shall have a Joint (Dual) Airworthiness Certification (JAC) consisting of a Safe to Fly (STF) letter from the USAF (for fixed and rotary wing), a Fleet Airworthiness Release (AWR) and an Aeromedical Certification letter from the U.S. Army
b. Device must be Food and Drug Administration (FDA) approved
c. Device shall provide two adjustable ranges of vacuum with a low adjustable vacuum range of ten (10) to a maximum of 200 mmHg for intermittent suction procedures and a high adjustable vacuum range of twenty (20) to at least 550 mmHg for continuous high vacuum procedures
d. Device must have greater than thirty (30) liters per minute of air flow rate at maximum vacuum
e. Device shall operate from 110-240 VAC, 50/60 Hz, and an internal rechargeable battery
f. Device must run continuously on battery power on a single charge on maximum suction for a minimum of two (2) hours
g. Device must fully charge at greater than or equal to ninety percent (90%) a depleted battery in less than or equal to six (6) hours
h. Device weight must be less than or equal to ten (10) pounds (lbs.)
i. Device must have a minimum two (2) year manufacturer warranty

A strategic market research effort was conducted by the Air Force Medical Evaluation Support Activity and U.S. Army Medical Material Development Activity from April 2024 to March 2025 to develop an understanding of markets, technologies, business developments and products of interest that may meet their set of validated minimum requirements. The following is a summary of the results:

The DLA Troop Support Biomedical Engineer performed additional market research. A Request for Information (RFI) for a Joint (Dual) Airworthiness Certified Suction Aspirator was issued on SAM.gov by DLA Troop Support in March of 2024 for ten (10) days. The RFI was then reissued on May 21, 2024 for thirty (30) days and closed June 20, 2024.

The Zoll 330M Suction Aspirator is the only device that meets all of the minimum requirement specified herein.

(5) The Zoll 330M Suction Aspirator is available on CEC SPE2D1-24-D-0018. The contract pricing has previously been determined fair and reasonable via The Contracting Officer has determined that the subject procurement's anticipated costs will be fair and reasonable.

(6) The Services will continue to perform market research on the availability of Suction Aspirators that may better meet their needs. When a superior technology is identified that warrants replacement of all equipment, the next generation Suction Aspirator is expected to be procured competitively through DLA Troop Support.

(7) The procurement of the Zoll 330M Suction Aspirators is expected to last approximately five (5) years, or until a superior device is introduced.

(8) In an effort to remove barriers to fair opportunity on subsequent acquisitions, DLA Troop Support will continue to perform market research of Suction Aspirators to locate other

acceptable sources for future acquisitions. However, any new device would be required to meet the Services' minimum requirements.

(9) As the Contracting Officer, I hereby certify that the information contained in this justification is accurate and complete to the best of my knowledge and belief.

[redacted]

Date

ANTHONY GIUNTA
Contracting Officer, FSD

I hereby certify that the requirements which form the basis of this justification are accurate, that these supplies meet the Government's minimum needs, and that this justification is accurate and complete to the best of my knowledge.

[redacted]

Date

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Biomedical Engineer, FSDC

I have reviewed and hereby approve this justification.

KENNY.WILLIAM.J.1228968826 Digitally signed by KENNY.WILLIAM.J.1228968826 Date: 2025.06.04 13:06:39 -04'00'

Date

WILLIAM J. KENNY
Executive Director
DLA Troop Support Contracting
and Acquisition Management