



NOTICE OF INTENT TO SOLE SOURCE

Date: April 4, 2023

Subject: Equipment to Measure Respiratory Depression in Clinical Studies

FDA ID: **NOI_FDA-SS-117667**

This is a notice that the U.S. Food & Drug Administration (FDA) intends to issue a purchase order to Hans Rudolph, Inc., located at 8325 Cole Parkway Shawnee, KS 66227. The Government intends to issue a sole source award in accordance with FAR 6.302-1, only one responsible source and no other supplies or services will satisfy agency requirements.

The NAICS Code is: 334516- Analytical Laboratory Instrument Manufacturing.

TECHNICAL REQUIREMENTS:

1. Shall have the ability to integrate with up to four different sensor modules;
2. Shall be equipped with differential pressure sensor modules with full scale ranges from 2 cm H₂O to 350 cm H₂O;
3. Shall include an absolute pressure sensor module for barometric pressure or altitude compensation;
4. Shall include up to five (5) calibration tables for each sensor module and + 5 or + 10 VDC analog input modules;
5. Shall include two (2) RS-232 serial ports for connection to an oximeter and CO₂ sensor;
6. Shall include provision for optional internal oxygen concentration sensor;
7. Shall be equipped with internal temperature and humidity and external temperature sensor;
8. Shall be capable of transmitting data over USB or wireless connection;
9. Shall have the ability to accommodate up to eight (8) data channels at up to 200 Hz rate, 8 TTL digital outputs and four (4) digital inputs;
10. Shall include digital outputs can be triggered on measured values;
11. Shall have available analog output module with four (4) outputs;
12. Shall be able to calibrate pneumotachs using a calibration syringe.
13. Shall include the following sensors:
 - a. Flow Module - Pressure sensor module with 16 mm H₂O range;
 - b. O₂ Sensor, Side Stream – capable of measuring internal oxygen concentration;
 - c. Heated PNT Flow Sensor;
 - d. CO₂ Sensor, Side Stream;
 - e. Adult finger sensor (reusable) - adult articulated spring finger clip sensor.

This notice is not a request for competitive proposals. However, any party that believes it can meet this requirement as stated herein may submit a written capability statement that clearly supports and demonstrates their ability to perform the requirement. Capability statements must be received by the response date and time of this notice. Submissions will be reviewed to determine if they can meet the requirement. A determination by the Government to compete this proposed contract based upon responses to this notice is solely within the discretion of the Government.

It is anticipated that an award will be issued to Hans Rudolph, Inc, within approximately five (5) days after the date of this notice unless the Government determines that any other organization has the capability to meet this requirement.

Response Date: April 11, 2023, by 8:00AM (EDT). Please email responses to Nicole Craig at nicole.craig@fda.hhs.gov. **No phone calls will be accepted.**