Smoke was seen coming in the top of the overhead door. The opening in the overhead door was sealed and the smoke test revealed no other problems.

For simplicity of example, the SF_6 detector was calibrated and adjusted to read directly SF_6 in ppms. The SF_6 flow meter was calibrated using a bubble meter.

Trial No.	Flow rate, lpm
1	0.903
2	0.908
3	0.899
4	0.900

The mean flow rate was ((0.903 + 0.908 + 0.899 + 0.900)/ 4)) 0.903 liters per minute (lpm).

The sampling probe was placed in the exhaust duct of the ventilation system and background samples were registered by the detector. The tubing (pure SF_6 outlet) from the flow meter was placed through the hood and into the duct of the ventilation system (upstream of the fan). Readings were as follows:

Task	Reading No.	Detector reading, ppm of SF_6
Background	1	0.0051
	2	0.0062
	3	0.0048
	4	0.0050
	5	0.0066
	6	0.0062
	7	0.0058
Start SF_6	8	6.3
	9	22.0
	10	21.8
	11	21.9
	12	21.7
	13	21.8
End	14	21.9

At least five consecutive measurements are needed; in this case, the last six data points were used. The eighth reading (6.3 ppm) does not reflect steady-state and was not used in determining the average. The mean concentration of SF_6 is 21.85 ppm (the average of those six points). The mean background value is 0.0057 ppm. These values were used to calculate the volumetric flow rate from Equation 1.

Q(exh)+0.903 / 28.3 / (21.85 − 0.0057) * 106 = 1460 cfm.

The average background value, 0.0057 ppm, was subtracted from the average 100% capture value, 21.85 ppm. In this case, the background value was negligible.

The same flow meter and SF_6 flow rate were used for the capture efficiency test. The tubing was removed from the ventilation system hood and connected to the 10-foot distribution plenum. Readings were as follows:

Task	Reading No.	Detector reading, ppm SF_6
Background	1	0.092
	2	0.084
	3	0.078
Start SF_6	4	28.1
	5	18.8
	6	19.6
	7	19.7
	8	20.9
	9	17.3
	10	19.4
	11	18.9
	12	19.6

At least five consecutive measurements are needed; in this case, the last eight will be used. The fourth reading (28.1 ppm) was high; in this case it reflects the flow controller overshooting the set point during the startup of SF_6 flow, and this point is not used in determining the average. The mean concentration of SF_6 is 19.28 ppm; the average background concentration was 0.0847 ppm.

Because we used the same SF_6 flow rate in both the exhaust volume test and the capture efficiency test, the calculations are simplified. From Equation 2, the capture efficiency is (19.28 − .0847) / (21.85 − 0.0057)* 100 = 87.9%.

This procedure was done four times with the following results:

Trial No.	100% capture, ppm SF_6	Capture efficiency, ppm SF_6	Capture efficiency, %
1	21.84	19.20	87.9
2	21.67	19.95	92.1
3	21.74	18.10	83.3
4	21.93	19.01	86.7

Statistics

Calculate the overall average of the means:

m = (87.9 + 92.1 + 83.3 + 86.7) / 4 = 87.5%

Calculate the estimated standard deviation:

s={((87.9 − 87.5)2 + (92.1 − 87.5)2 + (83.3 − 87.5)2 + (86.7 − 87.5)2) / (4 − 1)}0.5

={ (0.16 + 21.16 + 17.64 + 0.64) / 3}0.5 = 3.63

If the number of trials, n, is different from 4, then (n-1) is used in the denominator of this calculation and the numerator is the sum of all n squared differences, rather than just 4. Choose the number t (from the Student's t-distribution table at the 95th percentile) from the following table, based on the value of n:

t: 6.31 (n=2) 2.92 (n=3) 2.35 (n=4) 2.13 (n=5) 2.02 (n=6) 1.94 (n=7) 1.90 (n=8) 1.86 (n=9) 1.83 (n=10)

Calculate a test statistic (T):

T=m − t*s / n0.5

For this example: T = 87.5 − 2.35 * 3.63 / 40.5 = 83.2.

If T > 80.0, then decide (with 95% confidence) that efficiency is greater than 80%. In this example, we are 95% confident that the efficiency is greater than 80%.

If T ≤ 80.0, then the conclusion that the efficiency is greater than 80% cannot be made from these data.

Equipment

Smoke Test

Smoke generator
2 inch x 10 foot Schedule-40 PVC perforated distribution pipe

Tracer Gas Tests

Compressed cylinder of 99.98% SF_6 with regulator
Flow controller such as a precision rotameter
⅛-inch ID x 20-foot Teflon tubing and snap valves for SF_6 distribution
Primary Flow Calibrator
½-inch ID x 10-foot Copper tubing with 1/32-inch holes every 12 inches SF_6 distribution plenum
Gas monitor calibrated for SF_6
Calibration gases, nitrogen and at least one SF_6 concentration in nitrogen
12-liter Mylar gas sampling bags

Ventilation System Evaluation

Air Velocity Meter
Micro manometer w/Pitot Tube

Dated: September 27, 1996.

Linda Rosenstock,

Director, National Institute for Occupational Safety and Health Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–25314 Filed 10–2–96; 8:45 am]

BILLING CODE 4163–19–P

Food and Drug Administration

[Docket No. 94M–0404]

Thermo Cardiosystems, Inc.; Premarket Approval of the HeartMate® IP LVAS

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Thermo Cardiosystems, Inc., Woburn, MA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of HeartMate® IP LVAS. After reviewing

the recommendation of the Circulatory System Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of September 30, 1994, of the approval of the application.

DATES: Petitions for administrative review by November 4, 1996.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Rhona Shanker, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8262.

SUPPLEMENTARY INFORMATION: On March, 30 1992, Thermo Cardiosystems, Inc., Woburn, MA 01888, submitted to CDRH an application for premarket approval of the HeartMate® IP LVAS. The device is a left ventricular assist device and is indicated for use in patients, who are on the cardiac transplant list, as temporary mechanical circulatory support for nonreversible left ventricular failure as a bridge to cardiac transplantation. The patient should meet all of the following criteria: (1) Be an approved cardiac transplant candidate; (2) be on inotropes; (3) be on an intra-aortic balloon pump (if possible); and (4) have left atrial pressure or pulmonary capillary wedge pressure ≥ 20 mmHg with either: a. systolic blood pressure ≤ 80 mmHg, or b. cardiac index of ≤ 2.0 $1/min/m^2$.

On December 13, 1993, the Circulatory Devices Panel, an FDA advisory committee, reviewed and recommended approval of the application. On September 30, 1994, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before November 4, 1996, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: September 20, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96–25260 Filed 10–2–96; 8:45 am]

BILLING CODE 4160–01–F

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, contact the SAMHSA Reports Clearance Officer on (301) 443–8005.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: 1997 Inventory of Mental Health Services in Juvenile Justice Facilities—New—This survey will gather information for the first time about the availability of mental health services in the universe of approximately 3,100 juvenile justice facilities nationwide. State and national information will be collected about the organization of mental health services, characteristics of youth receiving these services, and mental health staffing patterns and costs. Automated collection techniques are not cost-effective for this survey. The total annual burden estimate is shown below.

	No. of respondents	No. of responses per respondent	Average burden per response (hrs.)	Total annual burden (hrs.)
Juvenile Justice Facilities	3,100	1	1.5	4,650