shall be withdrawn if either CBP or the airport authority gives 120 days written notice of termination to the other party. On January 15, 2009, CBP gave written notice to the Roswell Industrial Air Center in Roswell, New Mexico terminating their status as a user fee facility, in accordance with 19 CFR 122.15(c)(1). On November 6, 2008, the March Inland Port Airport Authority gave written notice terminating their MOA with CBP, in accordance with 19 CFR 122.15(c)(1).

On January 26, 2009, Capital City Airport notified CBP that it had officially changed its name to the Capital Region International Airport.

This document updates the list of user fee airports by deleting the Roswell Industrial Air Center in Roswell, New Mexico and the March Inland Port Airport in Riverside, California, and changing the name of the Capital City Airport in Lansing, Michigan to the Capital Region International Airport.

Inapplicability of Public Notice and Delayed Effective Date Requirements

Because this amendment merely updates the list of user fee airports to reflect a name change and to remove airports already approved for withdrawal by the Commissioner of CBP in accordance with 19 CFR 122.15(c)(1) and neither imposes additional burdens on, nor takes away any existing rights or privileges from, the public, pursuant to 5 U.S.C. 553(b)(B), notice and public procedure are unnecessary, and for the same reasons, pursuant to 5 U.S.C. 553(d)(3), a delayed effective date is not required.

The Regulatory Flexibility Act and Executive Order 12866

Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply. This amendment does not meet the criteria for a ''significant regulatory action'' as specified in Executive Order 12866.

Signing Authority

This document is limited to technical corrections of CBP regulations. Accordingly, it is being signed under the authority of 19 CFR 0.1(b).

List of Subjects in 19 CFR Part 122

Air carriers, Aircraft, Airports, Customs duties and inspection, Freight.

Amendments to Regulations

■ Part 122, Code of Federal Regulations (19 CFR part 122) is amended as set forth below:

PART 122—AIR COMMERCE REGULATIONS

■ 1. The authority citation for part 122 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 58b, 66, 1431, 1433, 1436, 1448, 1459, 1590, 1594, 1623, 1624, 1644, 1644a, 2071 note.

§ 122.15 [Amended]

■ 2. The listing of user fee airports in § 122.15(b) is amended as follows: by removing, in the ''Location'' column, ''Roswell, New Mexico'' and by removing on the same line, in the ''Name'' column, ''Roswell Air Industrial Center.''; by removing, in the ''Location'' column, ''Riverside, California'' and by removing on the same line, in the ''Name'' column, ''March Inland Port Airport.''; and, by removing, in the ''Name'' column, ''Capital City Airport'' and adding in its place ''Capital Region International Airport.''

Dated: October 15, 2009.

Jayson P. Ahern,

Acting Commissioner, Customs and Border Protection.

[FR Doc. E9–25318 Filed 10–20–09; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. FDA–2009–N–0472]

Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of the Cardiac Allograft Gene Expression Profiling Test Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing the classification of cardiac allograft gene expression profiling test systems into class II (special controls). The special control that will apply to the device is the guidance document entitled ''Class II Special Controls Guidance Document: Cardiac Allograft Gene Expression Profiling Test Systems.'' FDA classified the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control for this device.

DATES: This final rule is effective November 20, 2009. The classification was effective August 26, 2008.

FOR FURTHER INFORMATION CONTACT: Kellie B. Kelm, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5625, Silver Spring, MD 20993, 301–796–6145.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of FDA's regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing this classification (section 513(f)(2) of the act).

In accordance with section 513(f)(1) of the act, FDA issued an order on August 8, 2008, classifying the XDx AlloMap Test in class III because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device that was subsequently reclassified into class I or class II. On August 15, 2008, XDx, Inc., submitted a petition requesting

classification of the AlloMap Test under section 513(f)(2) of the act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in section 513(a)(1). Devices are to be classified into class II if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that the AlloMap Test can be classified in class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of safety and effectiveness of the device.

The device is assigned the generic name ''Cardiac allograft gene expression profiling test system.'' It is identified as a device that measures the RNA expression level of multiple genes and combines this information to yield a signature (pattern, classifier, index, score) to aid in the identification of a low probability of acute cellular rejection (ACR) in heart transplant recipients with stable allograft function.

FDA has identified the following issues of safety or effectiveness requiring special controls for a cardiac allograft gene expression profiling test system. Failure of this device to perform as indicated may lead to erroneous test results. False positive results will misclassify the patient into a higher risk group and false negative results will misclassify the patient into a lower risk group. Misclassification of ACR may lead to incorrect patient management with attendant psychological distress, inaccurate counseling, and suboptimal patient care.

FDA believes the class II special controls guidance document generally addresses the risks to health identified in the previous paragraph and will aid in mitigating potential risks by providing recommendations on labeling and validation of performance characteristics. The guidance document also provides information on how to meet 510(k) premarket notification submission requirements for the device. FDA believes that the special controls, in addition to general controls, provide reasonable assurances of the safety and effectiveness of the device type. Therefore, on August 26, 2008, FDA issued an order to the petitioner classifying the device into class II (Ref. 2). FDA is codifying this classification by adding § 862.1163.

Any firm submitting a premarket notification submission for a cardiac allograft gene expression profiling test system will need to address the issues covered in the special controls guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurance of safety and effectiveness.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, however, FDA has determined that premarket notification is necessary to provide a reasonable assurance of the safety and effectiveness of the device and, therefore, this type of device is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the cardiac allograft gene expression profiling test system they intend to market.

II. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because classification of this device into class II will relieve manufacturers of the cost of complying with the premarket approval requirements of section 515 of the act and may permit small potential competitors to enter the marketplace by lowering their costs, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $133 million, using the most current (2008) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Federal law includes an express preemption provision that preempts certain state requirements ''different from or in addition to'' certain Federal requirements applicable to devices. 21 U.S.C. 360k; See *Medtronic* v. *Lohr*, 518 U.S. 470 (1996); *Riegel* v. *Medtronic*, 128 S. Ct. 999 (2008). The special controls established by this final rule create ''requirements'' for specific medical devices under 21 U.S.C. 360k, even though product sponsors have some flexibility in how they meet those requirements. See *Papike* v. *Tambrands*, Inc., 107 F.3d 737, 740–42 (9th Cir. 1997).

V. Paperwork Reduction Act of 1995

This final rule establishes as special controls a guidance document that refers to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and

Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (the PRA). The collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB Control No. 0910–0120. The collections of information in 21 CFR part 801 and 21 CFR 809.10, regarding labeling, have been approved under OMB Control No. 0910–0485. The collections of information in 21 CFR part 820 have been approved under OMB Control No. 0910–0073.

VI. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from XDx, Inc., dated August 15, 2008.
2. Order classifying XDx AlloMap Test, dated August 26, 2008.

List of Subjects in 21 CFR Part 862

Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 862 is amended as follows:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 862 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 862.1163 is added to subpart B to read as follows:

§ 862.1163 Cardiac allograft gene expression profiling test system.

(a) *Identification.* A cardiac allograft gene expression profiling test system is a device that measures the ribonucleic acid (RNA) expression level of multiple genes and combines this information to yield a signature (pattern, classifier, index, score) to aid in the identification of a low probability of acute cellular rejection (ACR) in heart transplant recipients with stable allograft function.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Cardiac Allograft Gene Expression Profiling Test Systems.'' See § 862.1(d) for the availability of this guidance document.

Dated: October 9, 2009.

Jeffrey Shuren,

Acting Director, Center for Devices and Radiological Health.

[FR Doc. E9–25315 Filed 10–20–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2009–0895]

RIN 1625–AA11

Regulated Navigation Area; Portsmouth Naval Shipyard, Portsmouth, NH

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a regulated navigation area on the Piscataqua River near Portsmouth, NH. This temporary final rule places speed restrictions on all vessels transiting the navigable waters on the Piscataqua River, Portsmouth, NH near the Portsmouth Naval Shipyard between Henderson Point Light on Seavey Island and Badgers Island Buoy 14. This rule is necessary to provide for the safety of life on the navigable waters during ongoing ship construction.

DATES: This temporary final rule is effective from 7 a.m. on October 21, 2009, until 5 p.m. on November 15, 2009. This temporary final rule is enforceable with actual notice by Coast Guard personnel beginning October 15, 2009.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2009–0895 and are available online by going to *http://www.regulations.gov*, inserting USCG–2009–0895 in the ''Keyword'' box and then clicking ''Search.'' They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary final rule, call Lieutenant Junior Grade Laura van der Pol, Waterways Management Division Chief, U.S. Coast Guard Sector Northern New England, telephone 207–741–5421, e-mail *laura.k.vanderpol1@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the Portsmouth Naval Facility will be beginning diving operations in this area within a short timeframe thus making publication of a NPRM and Final Rule impractical. Further, this regulated navigation area is necessary to provide for the safety of the divers and others working in the area as wake from passing vessels could cause the ship to move erratically and unexpectedly, injuring the divers and their support crews. Not providing for the safety of the divers and others in the area is contrary to the public interest of creating a safe work environment.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register** as immediate action is necessary to provide for the safety of divers and workers on the vessel as well as to minimize the risk to commercial vessels and recreational boaters who transit the area. In addition to the reasons stated within this preamble, a delay in the effective date of this rule is contrary to the public's interest in ensuring the ship construction project continues as scheduled.

Background and Purpose

As part of ongoing ship construction projects at the Portsmouth Naval Shipyard, vessels are being launched, creating a period of particular sensitivity to the personnel and equipment involved. Specifically, divers will be working on the hull of a vessel for approximately four weeks beginning on October 15, 2009. Underwater work includes the removal and installation of heavy equipment. Unexpected and uncontrolled movement of the vessel while divers are in the water creates a significant risk of serious injury or death. Additionally, loading operations