on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

Does this AD involve a significant rule or regulatory action? For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the final evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. FAA amends § 39.13 by adding a new AD to read as follows:

2001–04–07 Socata-Groupe Aerospatiale: Amendment 39–12126; Docket No. 2000–CE–69–AD.

(a) *What airplanes are affected by this AD?* This AD affects Model TBM 700 airplanes, serial numbers 1 through 156, and 158 thru 163, that are certificated in any category.

(b) *Who must comply with this AD?* Anyone who wishes to operate any of the above airplanes must comply with this AD.

(c) *What problem does this AD address?* The actions specified by this AD are intended to prevent loss of propeller control because of hardening or blocking of the control cable, which could result in the inability to control propeller pitch and inability to feather the propeller. Such failure could lead to loss of airplane control.

(d) *What actions must I accomplish to address this problem?* To address this problem, you must accomplish the following:

Actions	Compliance	Procedures
Install a thermal protection sleeve on the propeller governor flexible cable.	Within the next 100 hours time-in-service (TIS) after April 13, 2001 (the effective date of this AD) or within the next 3 calendar months after April 13, 2001, whichever occurs first, unless already accomplished.	In accordance with Accomplishment Instructions of Socata Service Bulletin SB 70–084, dated September 2000, and the applicable maintenance manual.

(e) Can I comply with this AD in any other way? You may use an alternative method of compliance or adjust the compliance time if:

(1) Your alternative method of compliance provides an equivalent level of safety; and

(2) The Manager, Small Airplane Directorate, approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 1: This AD applies to each airplane identified in paragraph (a) of this AD, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact Karl Schletzbaum, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64016; telephone: (816) 329–4146; facsimile: (816) 329–4090.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(h) *Are any service bulletins incorporated into this AD by reference?* Actions required by this AD must be done in accordance with Socata Service Bulletin SB 70–084, dated September 2000. The Director of the Federal Register approved this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. You can get copies from Socata Groupe Aerospatiale, Customer Support, Aerodrome Tarbes-Ossun-Lourdes, BP 930–F65009 Tarbes Cedex, France; or the Product Support Manager, Socata-Groupe Aerospatiale, North Perry Airport, 7501 Pembroke Road, Pembroke Pines, Florida 33023. You can look at copies at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

(i) *When does this amendment become effective?* This amendment becomes effective on April 13, 2001.

Note 2: The subject of this AD is addressed in French AD 2000–430(A), dated November 15, 2000.

Issued in Kansas City, Missouri, on February 14, 2001.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–4399 Filed 2–27–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 01–ACE–1]

Amendment to Class E Airspace; Monroe City, MO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; request for comments.

SUMMARY: This action amends the Class E airspace area at Monroe City, MO. The FAA has developed Area Navigation (RNAV) Global Positioning System (GPS) Runway (RWY) 9 ORIGINAL, and RNAV (GPS) RWY 27 ORIGINAL Standard Instrument Approach Procedures (SIAP) to serve Monroe City Regional Airport, Monroe City, MO. Additional controlled airspace extending upward from 700 feet Above Ground Level (AGL) is needed to accommodate the SIAPs and for other Instrument Flight Rules (IFR) operations at this airport.

The intended effect of this rule is to provide controlled Class E airspace for aircraft executing the SIAPs and to segregate aircraft using instrument approach procedures in instrument

conditions from aircraft operating in visual conditions.

DATES: This direct final rule is effective on 0901 UTC, May 17, 2001.

Comments for inclusion in the Rules Docket must be received on or before March 25, 2001.

ADDRESSES: Send comments regarding the rule in triplicate to: Manager, Operations and Airspace Branch, Air Traffic Division, ACE–530, DOT Regional Headquarters Building, Federal Aviation Administration, Docket Number 01–ACE–1, 901 Locust, Kansas City, MO 64106.

The official docket may be examined in the Office of the Regional Counsel for the Central Regional at the same address between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours in the Air Traffic Division at the same address listed above.

FOR FURTHER INFORMATION CONTACT: Brenda Mumper, Air Traffic Division, Operations & Airspace Branch, ACE–520A, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (816) 329–2524.

SUPPLEMENTARY INFORMATION: The FAA has developed RNAV (GPS) RWY 9 ORIGINAL and RNAV (GPS) RWY 27 ORIGINAL SIAPs to serve Monroe City Regional Airport, Monroe City, MO. The amendment to Class E airspace at Monroe City, MO will provide additional controlled airspace at and above 700 feet AGL in order to contain the new SIAPs within controlled airspace, and thereby facilitate separation of aircraft operating under Instrument Flight Rules (IFR). The area will be depicted on appropriate aeronautical charts. Class E airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9H, dated September 1, 2000, and effective September 16, 2000, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Direct Final Rule Procedure

The FAA anticipates that this regulation will not result in adverse or negative comment and, therefore, is issuing it as a direct final rule. Previous actions of this nature have not been controversial and have not resulted in adverse comments or objections. The amendment will enhance safety for all flight operations by designating an area where VFR pilots may anticipate the presence of IFR aircraft at lower altitudes, especially during inclement weather conditions. A greater degree of safety is achieved by depicting the area on aeronautical charts. Unless a written adverse or negative comment, or a written notice of intent to submit an adverse or negative comment is received within the comment period, the regulation will become effective on the date specified above. After the close of the comment period, the FAA will publish a document in the **Federal Register** indicating that no adverse or negative comments were received and confirming the date on which the final rule will become effective. If the FAA does receive, within the comment period, an adverse or negative comment, or written notice of intent to submit such a comment, a document withdrawing the direct final rule will be published in the **Federal Register**, and a notice of proposed rulemaking may be published with a new comment period.

Comments Invited

Although this action is in the form of a final rule and was not preceded by a notice of proposed rulemaking, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES.** All communications received on or before the closing date for comments will be considered, and this rule may be amended or withdrawn in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of this action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy-related aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this action will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 01–ACE–1.'' The postcard will be date stamped and returned to the commenter.

Agency Findings

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

The FAA has determined that this regulation is noncontroversial and unlikely to result in adverse or negative comments. For the reasons discussed in the preamble, I certify that this regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Accordingly, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9H Airspace Designations and Reporting Points, dated September 1, 2000, and effective September 16, 2000, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ACE MO E5 Monroe City, MO

Monroe City Regional Airport, MO
(Lat. 39°38′04″ N., long. 91°43′37″ W.)
Quincy VORTAC
(Lat. 39°50′53″ N., long. 91°16′44″ W.)

That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of Monroe City Regional Airport and within 3.5 mules each side of the Quincy VORTAC 239° radial extending from 6.3-mile radius to 7 miles northeast of the airport.

* * * * *

Issued in Kansas City, MO, on February 8, 2001.

Richard L. Day,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 01–4677 Filed 2–27–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. 00P–1675]

Clinical Chemistry and Clinical Toxicology Devices; Classification of B–Type Natriuretic Peptide Test System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the B-type natriuretic peptide (BNP) test system into class II (special controls). The special control that will apply to this device is a guidance document entitled ''Class II Special Control Guidance Document for B–Type Natriuretic Peptide Premarket Notifications; Final Guidance for Industry and FDA Reviewers.'' The agency is taking this action in response to a petition submitted under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the Food and Drug Administration Modernization Act of 1997. The agency is classifying these devices into class II (special controls) in order to provide a reasonable assurance of the safety and effectiveness of the device.

DATES: This rule is effective February 28, 2001.

FOR FURTHER INFORMATION CONTACT: Jean M. Cooper, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1293.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of 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 and until 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 previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 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) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. 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 such classification.

In accordance with section 513(f)(1) of the act, FDA issued an order on November 13, 2000, classifying the BNP 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 II. On November 15, 2000, FDA received a petition submitted by Biosite Diagnostic, Inc., requesting classification of the BNP test system into class II under section 513(f)(2) of the act.

After review of the information submitted in the petition, FDA determined that the Biosite Diagnostics BNP test system can be classified in class II with the establishment of special controls. This device is intended to measure BNP in whole blood and plasma as an aid in the diagnosis of patients with congestive heart failure. FDA believes that class II special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

In addition to the general controls of the act, the Biosite Diagnostics BNP test system is subject to a special control guidance document entitled ''Class II Special Control Guidance Document for B–Type Natriuretic Peptide Premarket Notifications; Final Guidance for Industry and FDA Reviewers.''

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirement under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of this type of device and, therefore, the device is not exempt from the premarket notification requirements. The test is used in the diagnosis of patients with congestive heart failure. FDA review of data sets and labeling ensure that minimum levels of performance are obtained before marketing and are subject to impartial external quality control before labeling is put into place. Thus, persons who intend to market this device must submit to FDA a premarket notification submission containing information on the BNP test system before marketing the device.

On November 20, 2000, FDA issued an order to the petitioner classifying the Biosite Diagnostics BNP test system, and substantially equivalent devices of this generic type, into class II under the generic name, BNP test system. FDA identifies this generic type of device as a BNP test system, which is intended to aid in the diagnosis of congestive heart failure. FDA is codifying this device by adding § 862.1117. This order also identifies a special control applicable to this device ''Class II Special Control Guidance Document for B–Type Natriuretic Peptide Premarket Notifications; Final Guidance for Industry and FDA Reviewers.''

II. Electronic Access

In order to receive the draft guidance entitled ''Class II Special Control Guidance Document for B–Type Natriuretic Peptide Premarket Notifications; Final Guidance for Industry and FDA Reviewers'' via your fax machine, call the CDRH Facts on Demand System at 800–899–0381 or 301–827–0111 from a touch-tone