

it establishes temporary restricted airspace at Fort Sill, OK, enhancing safety and accommodating essential military training during the U.S. Army's MFIX 2018 exercise being held December 4 through 15, 2017.

#### History

On February 23, 2017, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) (82 FR 11417), Docket No. FAA-2016-9591, to establish a temporary restricted area designated to support hazardous training activities conducted during MFIX 2018 within the Fort Sill, OK, special use airspace (SUA) complex. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. No comments were received.

#### The Rule

The FAA is amending 14 CFR part 73 to establish temporary restricted area R-5602 in support of MFIX 2018 during the period of December 4 through 15, 2017, to contain hazardous laser activities demonstrating counter UAS capabilities. To effectively segregate nonparticipant air traffic from the hazardous activities associated with MFIX 2018 at Fort Sill, OK, the R-5602 lateral boundaries overlie the R-5601A, R-5601B, and a portion of R-5601F restricted areas and extend approximately 8 nautical miles (NM) east beyond the R-5601A and R-5601F eastern boundaries. R-5602 extends upward from 40,000 feet mean sea level (MSL) to 60,000 feet MSL, is activated daily by a Notice to Airmen (NOTAM), and is in effect only during the period of December 4 through December 15, 2017. This rule adds "daily" to the "Time of designation" for clarity.

Since R-5602 is a temporary area, it will not be depicted on the Dallas-Ft. Worth Sectional Aeronautical Chart or the IFR Enroute High Altitude Chart, H-6. However, a notice and graphic depiction will be published on the FAA's SUA Web site at <http://www.faa.gov/sua> and in the Notices to Airmen Publication (NTAP) available online at [http://www.faa.gov/air\\_traffic/publications/notices/](http://www.faa.gov/air_traffic/publications/notices/).

#### Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (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) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

#### Environmental Review

The FAA has determined that this action of establishing a temporary restricted area R-5602 which partially overlays portions of the R-5601 restricted area complex at Fort Sill, OK, qualifies for FAA adoption in accordance with FAA Order 1050.1F, paragraphs 8-2 and 9-2, *Adoption of Other Agencies' National Environmental Policy Act Documents, and Written Re-evaluations*, and 7400.2L, paragraph 32-2-3. The purpose of temporarily creating and utilizing the temporary Restricted Area (RA) is to safely segregate private and commercial aircraft from above-the-horizon hazardous laser activities while supporting the U.S. Army MFIX 2018 planned for November 27 through December 15, 2017 (the proposed temporary RA R-5602 would be active from December 4 through 15, 2017). The FAA, after conducting an independent review and evaluation of the United States Army's August 2017 Final Supplemental Environmental Assessment for the Temporary Creation and Utilization of Restricted Area R-5602 at Fort Sill, Oklahoma, has determined that the Army's Supplemental EA and its supporting documentation adequately assesses and discloses the environmental impacts of the proposed action, including evaluation of the establishment of airspace for temporary restricted airspace area R-5602. Based on the evaluation for potential environmental impact in the above-mentioned EA, the FAA, as the Cooperating Agency, concluded that adoption of the EA for the Temporary Creation and Utilization of Restricted Area R-5602 is authorized in accordance with 40 CFR 1506.3, *Adoption*. Accordingly, FAA adopts the Army's Supplemental EA and takes full responsibility for the scope and content that address the FAA's airspace establishment action.

#### List of Subjects in 14 CFR Part 73

Airspace, Prohibited areas, Restricted areas.

#### The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73 as follows:

#### PART 73—SPECIAL USE AIRSPACE

■ 1. The authority citation for part 73 continues to read as follows:

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

#### § 73.56 Oklahoma (Amended)

■ 2. § 73.56 is amended as follows:

\* \* \* \* \*

#### R-5602 Fort Sill, OK [Temporary]

**Boundaries.** Beginning at lat. 34°49'30" N., long. 98°08'43" W.; to lat. 34°36'36" N., long. 98°08'43" W.; to lat. 34°36'36" N., long. 98°17'01" W.; to lat. 34°38'15" N., long. 98°17'01" W.; to lat. 34°38'15" N., long. 98°37'57" W.; to lat. 34°40'54" N., long. 98°37'56" W.; to lat. 34°42'07" N., long. 98°37'20" W.; to lat. 34°43'21" N., long. 98°36'02" W.; to lat. 34°43'30" N., long. 98°35'40" W.; to lat. 34°45'03" N., long. 98°29'46" W.; to lat. 34°46'15" N., long. 98°25'01" W.; to lat. 34°47'00" N., long. 98°17'46" W.; to lat. 34°46'45" N., long. 98°17'01" W.; to lat. 34°49'30" N., long. 98°17'01" W.; to the point of beginning.

**Designated altitudes.** 40,000 feet MSL to 60,000 feet MSL.

**Time of designation.** December 4-15, 2017, daily, by NOTAM.

**Controlling agency.** FAA, Fort Worth ARTCC.

**Using agency.** U.S. Army, Commanding General, U.S. Army Fires Center of Excellence, Fort Sill, OK.

Issued in Washington, DC, on September 22, 2017.

**Rodger A. Dean, Jr.,**

*Manager, Airspace Policy Group.*

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#### SECURITIES AND EXCHANGE COMMISSION

#### 17 CFR Parts 227 and 230

[Release No. 33-10416]

#### Regulation Crowdfunding and Regulation A Relief and Assistance for Victims of Hurricane Harvey, Hurricane Irma, and Hurricane Maria

**AGENCY:** Securities and Exchange Commission.

**ACTION:** Interim final temporary rule.

**SUMMARY:** We are adopting interim final temporary rules for issuers subject to

reporting obligations pursuant to Regulation Crowdfunding and Regulation A in order to address the needs of companies directly or indirectly affected by Hurricane Harvey, Hurricane Irma, or Hurricane Maria. The temporary rules extend the filing deadlines for specified reports and forms due pursuant to Regulation Crowdfunding and Regulation A for certain issuers.

**DATES:** These rules are effective from September 28, 2017, through November 22, 2017.

**FOR FURTHER INFORMATION CONTACT:** Zachary O. Fallon, Special Counsel, or Amy Reischauer, Special Counsel, Office of Small Business Policy, Division of Corporation Finance, at (202) 551-3460, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-3628.

**SUPPLEMENTARY INFORMATION:** We are adopting amendments to Rule 202<sup>1</sup> of Regulation Crowdfunding<sup>2</sup> under the Securities Act of 1933 (the “Securities Act”)<sup>3</sup> and Rule 257<sup>4</sup> of Regulation A<sup>5</sup> under the Securities Act as interim final temporary rules.

### I. Introduction

In late August 2017, Hurricane Harvey caused catastrophic damage along the Texas and Louisiana coast, in early September 2017, Hurricane Irma caused catastrophic damage to the U.S. Virgin Islands, Puerto Rico and the Florida coast, and, in mid-September 2017, Hurricane Maria caused additional catastrophic damage to the U.S. Virgin Islands and Puerto Rico. The storms and subsequent flooding have displaced individuals and businesses and disrupted communications and transportation across the affected regions. We are adopting these interim final temporary rules to address the needs of companies directly or indirectly affected by Hurricane Harvey, Hurricane Irma, or Hurricane Maria or their respective aftermaths that are subject to reporting obligations pursuant to Regulation Crowdfunding or Regulation A.

Section 28 of the Securities Act provides that the Commission may, by rule or regulation, “conditionally or unconditionally exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions, from any provision or provisions of this title or of any rule or regulation issued under this title, to the

extent that such exemption is necessary or appropriate in the public interest, and is consistent with the protection of investors.”<sup>6</sup>

### II. Temporary Relief From Filing Requirements for Issuers Subject to the Reporting Obligations of Regulation Crowdfunding or Regulation A

The lack of communications, transportation, electricity, facilities, and available staff and professional advisors as a result of Hurricane Harvey, Hurricane Irma, and Hurricane Maria could hamper the efforts of companies with reporting obligations to meet their filing deadlines pursuant to Regulation Crowdfunding or Regulation A. At the same time, investors have an interest in the timely availability of required information about these companies. While the Commission believes that the temporary relief from filing requirements provided by the amendments to Rule 202 of Regulation Crowdfunding<sup>7</sup> and Rule 257 of Regulation A<sup>8</sup> is both necessary in the public interest and consistent with the protection of investors, we remind companies that are the subject of the relief provided in these interim final temporary rules to continue to evaluate their obligations to make materially accurate and complete disclosures in accordance with the anti-fraud provisions of the federal securities laws.

Accordingly, pursuant to Section 28 of the Securities Act, we are adopting interim final temporary rules providing that an issuer subject to the reporting requirements of either Regulation Crowdfunding or Regulation A is exempt from any requirement to file specified reports or forms with the Commission where the conditions below are satisfied:

(a) The issuer is not able to meet a filing deadline due to Hurricane Harvey, Hurricane Irma, or Hurricane Maria or their respective aftermaths;

(b)(i) For issuers affected by Hurricane Harvey, the issuer files with the Commission, on or before October 27, 2017, the report or form required to be filed pursuant to either Regulation Crowdfunding or Regulation A during the period from and including August 25, 2017 to and including October 26, 2017;

(ii) For issuers affected by Hurricane Irma, the issuer files with the Commission, on or before November 8, 2017, the report or form required to be

filed pursuant to either Regulation Crowdfunding or Regulation A during the period from and including September 6, 2017 to and including November 7, 2017; or

(ii) For issuers affected by Hurricane Maria, the issuer files with the Commission, on or before November 22, 2017, the report or form required to be filed pursuant to either Regulation Crowdfunding or Regulation A during the period from and including September 20, 2017 to and including November 21, 2017; and

(c) In any such report or form, the issuer discloses that it is relying on the interim final temporary rules and states the reasons why, in good faith, it could not file such report or form on a timely basis.

For Regulation Crowdfunding, the relief includes annual reports on Form C-AR, progress updates on Form C-U, and termination of reporting on Form C-TR. For Regulation A, the relief includes post-qualification amendments required at least every 12 months after the qualification date to include updated financial statements, annual reports on Form 1-K, semi-annual reports on Form 1-SA, special financial reports on Forms 1-K or 1-SA, current reports on Form 1-U, and exit reports on Form 1-Z.

### III. Economic Analysis

Regulation Crowdfunding and Regulation A permit offers and sales of securities without registration under the Securities Act, subject to certain limitations and conditions, including compliance with ongoing reporting requirements. Based on staff analysis, approximately 150 filers publicly filed Regulation A offering statements between June 19, 2015 (the effective date of the most recent Regulation A amendments<sup>9</sup>) and August 31, 2017 that have been qualified as of September 15, 2017. Approximately 418 issuers initiated Regulation Crowdfunding offerings with Form C filings between May 16, 2016 and August 31, 2017, excluding issuers that have withdrawn offerings.<sup>10</sup> Approximately 28 registered intermediaries, including registered funding portals and registered broker-dealers, have participated in Regulation Crowdfunding offerings with Form C filings between May 16, 2016 and August 31, 2017, which includes offerings that may have been

<sup>9</sup> SEC Rel. No. 33-9741 (Mar. 25, 2015) [80 FR 21806 (Apr. 20, 2015)].

<sup>10</sup> These figures overstate the number of issuers with obligations to file annual reports under Regulation Crowdfunding, because they do not exclude issuers that have failed to raise the target amount or have exited the reporting regime.

<sup>1</sup> 17 CFR 227.202.

<sup>2</sup> 17 CFR 227 *et seq.*

<sup>3</sup> 15 U.S.C. 77a *et seq.*

<sup>4</sup> 17 CFR 230.257.

<sup>5</sup> 17 CFR 230.251 through 230.263.

<sup>6</sup> 15 U.S.C. 77z-3.

<sup>7</sup> See Rule 202(c) of Regulation Crowdfunding. 17 CFR 227.202(c).

<sup>8</sup> See Rule 257(f) of Regulation A. 17 CFR 230.257(f).

subsequently terminated or failed to reach the target amount.

We lack the data to estimate the number of investors in Regulation A or Regulation Crowdfunding offerings that could be affected if issuers rely on the relief provided by the interim final temporary rules, because information on the number of investors is generally not required to be disclosed in periodic or current reports required under Regulation A or in periodic reports or progress updates required under Regulation Crowdfunding.<sup>11</sup>

We are mindful of the costs and benefits of the interim final temporary rules.<sup>12</sup> We believe the interim final temporary rules will benefit issuers that have an obligation to file specified reports with the Commission pursuant to either Regulation Crowdfunding or Regulation A and have been adversely affected by Hurricane Harvey, Hurricane Irma, or Hurricane Maria or their respective aftermaths by permitting them to take additional time to meet their reporting obligations. We expect the relief provided by the interim final temporary rules will benefit issuers that, absent the relief, would not be able to avail themselves of the exemption from registration under Regulation Crowdfunding or Regulation A because the timely filing of required reports is a condition to the exemptions. In the absence of this relief, issuers could incur prohibitively high costs in an attempt to meet filing deadlines given the lack of communications, transportation, electricity, facilities, and available staff and professional advisors.

The requirement for an issuer to disclose that it is relying on Rule 202(c) of Regulation Crowdfunding or Rule 257(f) of Regulation A and to state the reasons why, in good faith, it could not file a report or form on a timely basis may impose minimal additional costs on issuers availing themselves of this relief. However, we believe that these minimal costs are justified in light of the significant negative implications of not being able to rely on the exemption and the prohibitively high costs an issuer may incur in attempting to file in a timely manner.

We also acknowledge that there may be costs imposed on investors, intermediaries, and other market

participants due to delayed access to information about offerings conducted in reliance on Regulation A and Regulation Crowdfunding. Generally, reporting requirements strengthen investor protection and decrease the extent of information asymmetries between issuers and investors. Ongoing reporting provides investors with periodically updated information, allowing them to assess investment opportunities based on the information provided and their level of risk tolerance, resulting in better informed investment decisions and improved allocative efficiency. Given that the interim final temporary rules allow for delayed reporting for a limited time period and only under specified conditions, we do not believe such costs will be significant.

The interim final temporary rules will not substantially affect competition or capital formation. We acknowledge the possibility that the interim final temporary rules may have a minor impact on efficiency. On the one hand, as noted above, the delay in reporting could marginally affect allocative efficiency to the extent that it allows information asymmetries between investors and issuers to persist for the length of time of the delay. On the other hand, we expect efficiency gains to the extent that the interim final temporary rules allow issuers to continue to rely on either of the exemptions from registration that would not be available if one of the required reports that is a condition to the exemptions was not filed in a timely manner, or to the extent the issuers are able to avoid paying a premium to service providers in an attempt to file in a timely manner by delaying reporting during the specified relief period.

As an alternative to the relief specified in the interim final temporary rules, we could have considered a longer or shorter relief period. While a shorter period would have reduced the costs to investors of asymmetric information, it would also reduce the benefits of the interim final temporary rules to issuers. Similarly, a longer period would increase the costs to investors. We believe that the approximately nine-week delay in the interim final temporary rules is appropriate given the potential impact Hurricane Harvey, Hurricane Irma, or Hurricane Maria or their respective aftermaths could have on the efforts of companies to meet filing deadlines pursuant to Regulation Crowdfunding and Regulation A.

#### IV. Procedural and Other Matters

The Administrative Procedure Act (“APA”) generally requires an agency to publish notice of a rulemaking in the **Federal Register** and provide an opportunity for public comment. This requirement does not apply, however, if the agency “for good cause finds . . . that notice and public procedure are impracticable, unnecessary, or contrary to the public interest.”<sup>13</sup> The APA also generally requires that an agency publish an adopted rule in the **Federal Register** at least 30 days before it becomes effective. This requirement does not apply, however, if the agency finds good cause for making the rule effective sooner.<sup>14</sup>

Given the temporary nature of the relief contemplated by the interim final temporary rules and the significant and immediate impacts of Hurricane Harvey, Hurricane Irma, and Hurricane Maria and their aftermaths on issuers in affected areas, as discussed above, the Commission finds that good cause exists to dispense with notice and comment as impracticable and unnecessary, and to act immediately to amend Rule 202 of Regulation Crowdfunding and Rule 257 of Regulation A.<sup>15</sup> Further, the interim final temporary rules will not affect the burden or cost estimates associated with existing collections of information under Regulation Crowdfunding and Regulation A for purposes of the Paperwork Reduction Act of 1995.<sup>16</sup>

#### V. Statutory Basis and Text of Amendments

We are adopting amendments to Rule 202 of Regulation Crowdfunding and Rule 257 of Regulation A under the authority set forth in the Securities Act (15 U.S.C. 77a *et seq.*), particularly, Section 28 thereof.

#### List of Subjects

##### 17 CFR Part 227

Crowdfunding, Funding portals, Intermediaries, Reporting and recordkeeping requirements, Securities.

<sup>13</sup> 5 U.S.C. 553(b)(3)(B).

<sup>14</sup> 5 U.S.C. 553(d)(3).

<sup>15</sup> This finding also satisfies the requirements of 5 U.S.C. 808(2), allowing the interim final temporary rules to become effective notwithstanding the requirement of 5 U.S.C. 801 (if a federal agency finds that notice and public comment are impractical, unnecessary or contrary to the public interest, a rule shall take effect at such time as the federal agency promulgating the rule determines). The interim final temporary rules also do not require analysis under the Regulatory Flexibility Act. *See* 5 U.S.C. 604(a) (requiring a final regulatory flexibility analysis only for rules required by the APA or other law to undergo notice and comment).

<sup>16</sup> 44 U.S.C. 3501 *et seq.*

<sup>11</sup> Regulation A issuers that file Form 1-Z to suspend reporting are required to disclose the number of shareholders of record.

<sup>12</sup> Section 2(b) of the Securities Act [15 U.S.C. 77b(b)] requires the Commission, when engaging in rulemaking where it is required to consider or determine whether an action is necessary or appropriate in the public interest, to consider, in addition to the protection of investors, whether the action will promote efficiency, competition, and capital formation.

## 17 CFR Part 230

Reporting and recordkeeping requirements, Securities.

In accordance with the foregoing, title 17, chapter II of the Code of Federal Regulations is amended as follows:

**PART 227—REGULATION CROWDFUNDING, GENERAL RULES AND REGULATIONS**

■ 1. The authority citation for part 227 is revised to read as follows:

**Authority:** 15 U.S.C. 77d, 77d–1, 77s, 77z–3, 78c, 78o, 78q, 78w, 78mm, and Pub. L. 112–106, secs. 301–305, 126 Stat. 306 (2012).

■ 2. Amend § 227.202 by adding paragraph (c) to read as follows:

**§ 227.202 Ongoing reporting requirements.**

(c) *Temporary relief from certain reporting requirements.* (1) An issuer that is not able to meet a filing deadline for any report or form required to be filed by this section (Rule 202), Rule 203(a)(3) (§ 227.203(a)(3)), or Rule 203(b) (§ 227.203(b)), as applicable:

(i) During the period from and including August 25, 2017 to and including October 26, 2017 due to Hurricane Harvey and its aftermath shall be deemed to have satisfied the filing deadline for such report or form if the issuer files such report or form with the Commission on or before October 27, 2017;

(ii) During the period from and including September 6, 2017 to and including November 7, 2017 due to Hurricane Irma and its aftermath shall be deemed to have satisfied the filing deadline for such report or form if the issuer files such report or form with the Commission on or before November 8, 2017; or

(iii) During the period from and including September 20, 2017 to and including November 21, 2017 due to Hurricane Maria and its aftermath shall be deemed to have satisfied the filing deadline for such report or form if the issuer files such report or form with the Commission on or before November 22, 2017.

(2) In any report or form filed pursuant to paragraph (c)(1) of this section, the issuer must disclose that it is relying on this paragraph (c) (Rule 202(c) of Regulation Crowdfunding) and state the reasons why, in good faith, it could not file such report or form on a timely basis.

**PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933**

■ 3. The authority citation for part 230 continues to read in part as follows:

**Authority:** 15 U.S.C. 77b, 77b note, 77c, 77d, 77f, 77g, 77h, 77j, 77r, 77s, 77z–3, 77sss, 78c, 78d, 78j, 78l, 78m, 78n, 78o, 78o–7 note, 78t, 78w, 78ll(d), 78mm, 80a–8, 80a–24, 80a–28, 80a–29, 80a–30, and 80a–37, and Pub. L. 112–106, sec. 201(a), sec. 401, 126 Stat. 313 (2012), unless otherwise noted.

■ 4. Amend § 230.257 by adding paragraph (f) to read as follows:

**§ 230.257 Periodic and current reporting; exit report.**

(f) *Temporary relief from ongoing reporting requirements.* (1) An issuer that is not able to meet a filing deadline for any report or form required to be filed by Rule 252(f)(2)(i) (§ 230.252(f)(2)(i)) or this section (Rule 257), as applicable:

(i) During the period from and including August 25, 2017 to and including October 26, 2017 due to Hurricane Harvey and its aftermath shall be deemed to have satisfied the filing deadline for such report or form if the issuer files such report or form with the Commission on or before October 27, 2017;

(ii) During the period from and including September 6, 2017 to and including November 7, 2017 due to Hurricane Irma and its aftermath shall be deemed to have satisfied the filing deadline for such report or form if the issuer files such report or form with the Commission on or before November 8, 2017; or

(iii) During the period from and including September 20, 2017 to and including November 21, 2017 due to Hurricane Maria and its aftermath shall be deemed to have satisfied the filing deadline for such report or form if the issuer files such report or form with the Commission on or before November 22, 2017.

(2) In any report or form filed pursuant to paragraph (f)(1) of this section, the issuer must disclose that it is relying on this paragraph (f) (Rule 257(f) of Regulation A) and state the reasons why, in good faith, it could not file such report or form on a timely basis.

By the Commission.

Dated: September 27, 2017.

**Brent J. Fields,**  
Secretary.

[FR Doc. 2017–21094 Filed 9–28–17; 4:15 pm]

**BILLING CODE 8011–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 876**

[Docket No. FDA–2017–N–5153]

**Medical Devices; Gastroenterology-Urology Devices; Classification of the High Intensity Ultrasound System for Prostate Tissue Ablation**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA or we) is classifying the high intensity ultrasound system for prostate tissue ablation into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the high intensity ultrasound system for prostate tissue ablation's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

**DATES:** This order is effective October 2, 2017. The classification was applicable on October 9, 2015.

**FOR FURTHER INFORMATION CONTACT:** John Baxley, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G210, Silver Spring, MD 20993–0002, 301–796–6549, [john.baxley@fda.hhs.gov](mailto:john.baxley@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Upon request, FDA has classified the high intensity ultrasound system for prostate tissue ablation as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains