(ii) Reserved.

(3) For service information identified in this AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *http://www.airbus.com.*

(4) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on February 22, 2018.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–04265 Filed 3–6–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 157

[Docket No. RM81–19–000]

Natural Gas Pipelines; Project Cost and Annual Limits

AGENCY: Federal Energy Regulatory Commission, Energy.

ACTION: Final rule.

SUMMARY: Pursuant to the authority delegated by the Commission's regulations, the Director of the Office of Energy Projects (OEP) computes and publishes the project cost and annual limits for natural gas pipelines blanket construction certificates for each calendar year.

DATES: This final rule is effective March 7, 2018 and establishes cost limits applicable from January 1, 2018 through December 31, 2018.

FOR FURTHER INFORMATION CONTACT: Richard W. Fole, Chief, Certificates Branch 1, Division of Pipeline Certificates, (202) 502–8955.

SUPPLEMENTARY INFORMATION: Section 157.208(d) of the Commission's Regulations provides for project cost limits applicable to construction, acquisition, operation and miscellaneous rearrangement of facilities (Table I) authorized under the blanket certificate procedure (Order No. 234, 19 FERC ¶ 61,216). Section 157.215(a) specifies the calendar year dollar limit which may be expended on underground storage testing and development (Table II) authorized under the blanket certificate. Section 157.208(d) requires that the ''limits specified in Tables I and II shall be adjusted each calendar year to reflect the 'GDP implicit price deflator' published by the Department of Commerce for the previous calendar year.''

Pursuant to § 375.308(x)(1) of the Commission's Regulations, the authority for the publication of such cost limits, as adjusted for inflation, is delegated to the Director of the Office of Energy Projects. The cost limits for calendar year 2018, as published in Table I of § 157.208(d) and Table II of 157.215(a), are hereby issued.

Effective Date

This final rule is effective March 7, 2018. The provisions of 5 U.S.C. 804 regarding Congressional review of Final Rules does not apply to the Final Rule because the rule concerns agency procedure and practice and will not substantially affect the rights or obligations of non-agency parties. The Final Rule merely updates amounts published in the Code of Federal Regulations to reflect the Department of Commerce's latest annual determination of the Gross Domestic Product (GDP) implicit price deflator, a mathematical updating required by the Commission's existing regulations.

List of Subjects in 18 CFR Part 157

Administrative practice and procedure, Natural gas, Reporting and recordkeeping requirements.

Issued: February 27, 2018.

Terry L. Turpin,

Director, Office of Energy Projects.

Accordingly, 18 CFR part 157 is amended as follows:

PART 157—[AMENDED]

■ 1. The authority citation for part 157 continues to read as follows:

Authority: 15 U.S.C. 717–717w, 3301–3432; 42 U.S.C. 7101–7352.

■ 2. Table I in § 157.208(d) is revised to read as follows:

§ 157.208 Construction, acquisition, operation, replacement, and miscellaneous rearrangement of facilities.

* * * * *

(d) * * *

TABLE I TO PART 157

Year	Limit	
	Auto. proj. cost limit (Col. 1)	Prior notice proj. cost limit (Col. 2)
1982	$4,200,000	$12,000,000
1983	4,500,000	12,800,000
1984	4,700,000	13,300,000
1985	4,900,000	13,800,000
1986	5,100,000	14,300,000
1987	5,200,000	14,700,000
1988	5,400,000	15,100,000
1989	5,600,000	15,600,000
1990	5,800,000	16,000,000
1991	6,000,000	16,700,000
1992	6,200,000	17,300,000
1993	6,400,000	17,700,000
1994	6,600,000	18,100,000
1995	6,700,000	18,400,000
1996	6,900,000	18,800,000
1997	7,000,000	19,200,000
1998	7,100,000	19,600,000
1999	7,200,000	19,800,000
2000	7,300,000	20,200,000
2001	7,400,000	20,600,000
2002	7,500,000	21,000,000
2003	7,600,000	21,200,000
2004	7,800,000	21,600,000
2005	8,000,000	22,000,000
2006	9,600,000	27,400,000
2007	9,900,000	28,200,000
2008	10,200,000	29,000,000
2009	10,400,000	29,600,000
2010	10,500,000	29,900,000
2011	10,600,000	30,200,000
2012	10,800,000	30,800,000
2013	11,000,000	31,400,000
2014	11,200,000	31,900,000
2015	11,400,000	32,400,000
2016	11,600,000	32,800,000
2017	11,800,000	33,200,000
2018	12,000,000	33,800,000

* * * * *

■ 3. Table II in § 157.215(a)(5) is revised to read as follows:

§ 157.215 Underground storage testing and development.

(a) * * *

(5) * * *

TABLE II TO PART 157

Year	Limit
1982	$2,700,000
1983	2,900,000
1984	3,000,000
1985	3,100,000
1986	3,200,000
1987	3,300,000
1988	3,400,000
1989	3,500,000
1990	3,600,000
1991	3,800,000
1992	3,900,000
1993	4,000,000
1994	4,100,000
1995	4,200,000
1996	4,300,000

TABLE II TO PART 157—Continued

Year	Limit
1997	4,400,000
1998	4,500,000
1999	4,550,000
2000	4,650,000
2001	4,750,000
2002	4,850,000
2003	4,900,000
2004	5,000,000
2005	5,100,000
2006	5,250,000
2007	5,400,000
2008	5,550,000
2009	5,600,000
2010	5,700,000
2011	5,750,000
2012	5,850,000
2013	6,000,000
2014	6,100,000
2015	6,200,000
2016	6,300,000
2017	6,400,000
2018	6,500,000

* * * * *

[FR Doc. 2018–04413 Filed 3–6–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2018–N–0387]

Medical Devices; General and Plastic Surgery Devices; Classification of the Extracorporeal Shock Wave Device for Treatment of Chronic Wounds

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the extracorporeal shock wave device for treatment of chronic wounds 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 extracorporeal shock wave device for treatment of chronic wounds' 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 March 7, 2018. The classification was applicable on December 28, 2017.

FOR FURTHER INFORMATION CONTACT: Mehmet Kosoglu, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1572, Silver Spring, MD 20993–0002, 301–796–6194, *Mehmet.Kosoglu@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the extracorporeal shock wave device for treatment of chronic wounds 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 within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act to a predicate device that does not require premarket approval (see 21 U.S.C. 360c(i)). We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act and part 807 (21 U.S.C. 360(k) and 21 CFR part 807, respectively).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA shall classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On July 25, 2016, Sanuwave, Inc., submitted a request for De Novo classification of the dermaPACE System. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices 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 that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA