

including the limitation imposed on the amount to be paid.

§ 725.716 How should a miner prepare and submit requests for reimbursement for covered medical expenses and transportation costs?

(a) If a miner has paid bills for a medical service or treatment covered under § 725.701 and seeks reimbursement for those expenses, he or she may submit a request for reimbursement on Form OWCP-915, together with an itemized bill. The reimbursement request must be accompanied by evidence that the provider received payment for the service from the miner and a statement of the amount paid. Acceptable evidence that payment was received includes, but is not limited to, a copy of the miner's canceled check (both front and back) or a copy of the miner's credit card receipt.

(b) OWCP may waive the requirements of paragraph (a) of this section if extensive delays in the filing or the adjudication of a claim make it unusually difficult for the miner to obtain the required information.

(c) Reimbursements for covered medical services paid by a miner generally will be no greater than the maximum allowable charge for such service as determined under §§ 725.707-725.711.

(d) A miner will be only partially reimbursed for a covered medical service if the amount he or she paid to a provider for the service exceeds the maximum charge allowable. If this happens, OWCP will advise the miner of the maximum allowable charge for the service in question and of his or her responsibility to ask the provider to refund to the miner, or credit to the miner's account, the amount he or she paid which exceeds the maximum allowable charge.

(e) If the provider does not refund to the miner or credit to his or her account the amount of money paid in excess of the charge allowed by OWCP, the miner should submit documentation to OWCP of the attempt to obtain such refund or credit. OWCP may make reasonable reimbursement to the miner after reviewing the facts and circumstances of the case.

(f) If a miner has paid transportation costs or other incidental expenses related to covered medical services under this part, the miner may submit a request for reimbursement on Form OWCP-957 or OWCP-915, together with proof of payment.

§ 725.717 What are the time limitations for requesting payment or reimbursement for covered medical services or treatments?

OWCP will pay providers and reimburse miners promptly for all bills received on an approved form and in a timely manner. However, absent good cause, no bill will be paid for expenses incurred if the bill is submitted more than one year beyond the end of the calendar year in which the expense was incurred or the service or supply was provided, or more than one year beyond the end of the calendar year in which the miner's eligibility for benefits is finally adjudicated, whichever is later. A provider may not request reimbursement from a miner for a bill denied by OWCP due to late submission of the bill by the provider.

§ 725.718 How are disputes concerning medical benefits resolved?

(a) If a dispute develops concerning medical services or treatments or their payment under this part, OWCP must attempt to informally resolve the dispute. OWCP may, on its own initiative or at the request of the responsible operator or its insurance carrier, order the claimant to submit to an examination by a physician selected by OWCP.

(b) If a dispute cannot be resolved informally, OWCP will refer the case to the Office of Administrative Law Judges for a hearing in accordance with this part. Any such hearing concerning authorization of medical services or treatments must be scheduled at the earliest possible time and must take precedence over all other hearing requests except for other requests under this section and as provided by § 727.405 of this subchapter (*see* § 725.4(d)). During the pendency of such adjudication, OWCP may order the payment of medical benefits prior to final adjudication under the same conditions applicable to benefits awarded under § 725.522.

(c) In the development or adjudication of a dispute over medical benefits, the adjudication officer is authorized to take whatever action may be necessary to protect the health of a totally disabled miner.

(d) Any interested medical provider may, if appropriate, be made a party to a dispute under this subpart.

§ 725.719 What is the objective of vocational rehabilitation?

The objective of vocational rehabilitation is the return of a miner who is totally disabled by pneumoconiosis to gainful employment commensurate with such miner's physical impairment. This objective

may be achieved through a program of re-evaluation and redirection of the miner's abilities, or retraining in another occupation, and selective job placement assistance.

§ 725.720 How does a miner request vocational rehabilitation assistance?

Each miner who has been determined entitled to receive benefits under part C of title IV of the Act must be informed by OWCP of the availability and advisability of vocational rehabilitation services. If such miner chooses to avail himself or herself of vocational rehabilitation, his or her request will be processed and referred by OWCP vocational rehabilitation advisors pursuant to the provisions of §§ 702.501 through 702.508 of this chapter as is appropriate.

Dated: June 5, 2018.

Julia K. Hearthway,
Director, Office of Workers' Compensation Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA-2018-N-1928]

Medical Devices; Immunology and Microbiology Devices; Classification of the Brain Trauma Assessment Test

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the brain trauma assessment test 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 brain trauma assessment test'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 June 14, 2018. The classification was applicable on February 14, 2018.

FOR FURTHER INFORMATION CONTACT: Erin Cutts, Center for Devices and Radiological Health, Food and Drug

Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5618, Silver Spring, MD 20993-0002, 301-796-6307, erin.cutts@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the brain trauma assessment test 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 (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. 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 (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

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 placed 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 August 28, 2017, Banyan Biomarkers, Inc., submitted a request for De Novo classification of the Banyan BTI. 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 has determined that these special controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on February 14, 2018, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 866.5830. We have named the generic type of device brain trauma assessment test, and it is identified as a device that consists of reagents used to detect and measure brain injury biomarkers in human specimens. The measurements aid in the evaluation of patients with suspected mild traumatic brain injury in conjunction with other clinical information to assist in determining the need for head imaging per current standard of care.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—BRAIN TRAUMA ASSESSMENT TEST RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Inaccurate test results that provide false positive or false negative results.	General controls and special control (1) (21 CFR 866.5830(b)(1)).
Failure to correctly interpret test results can lead to false positive or false negative results.	General controls and special control (2) (21 CFR 866.5830(b)(2)).

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance

of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with

the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to

premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of 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.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. 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 collections of information in the guidance document “De Novo Classification Process (Evaluation of Automatic Class III Designation)” have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR parts 801 and 809, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, 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 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for part 866 continues to read as follows:

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

■ 2. Add § 866.5830 to subpart F to read as follows:

§ 866.5830 Brain trauma assessment test.

(a) *Identification.* A brain trauma assessment test is a device that consists of reagents used to detect and measure brain injury biomarkers in human specimens. The measurements aid in the evaluation of patients with

suspected mild traumatic brain injury in conjunction with other clinical information to assist in determining the need for head imaging per current standard of care.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The 21 CFR 809.10(b) compliant labeling must include detailed descriptions of and results from performance testing conducted to evaluate precision, accuracy, linearity, analytical sensitivity, interference, and cross-reactivity. This information must include the following:

(i) Performance testing of device precision must, at minimum, use one unmodified clinical specimen from the intended use population with concentration of the brain injury biomarker(s) near the medical decision point. Contrived specimens that have been generated from pooling of multiple samples or spiking of purified analyte to cover the measuring range may be used, but the contrived samples must be prepared to mimic clinical specimens as closely as possible. This testing must evaluate repeatability and reproducibility using a protocol from an FDA-recognized standard.

(ii) Device performance data must be demonstrated through a clinical study and must include the following:

(A) Data demonstrating clinical validity including the clinical sensitivity and specificity, and positive and negative predictive value of the test in the intended use population of patients with suspected mild traumatic brain injury (*i.e.*, Glasgow Coma Score (GCS) of 13–15), or equivalent standard of care for determination of severity of traumatic brain injury (TBI).

(B) Study must be performed using the operators and in settings that are representative of the types of operators and settings for which the device is intended to be used.

(C) All eligible subjects must meet the well-defined study inclusion and exclusion criteria that define the intended use population. The prevalence of diseased or injured subjects in the study population must reflect the prevalence of the device’s intended use population, or alternatively, statistical measures must be used to account for any bias due to enrichment of subpopulations of the intended use population.

(D) All eligible subjects must have undergone a head computerized tomography (CT) scan or other appropriate clinical diagnostic standard used to determine the presence of an intracranial lesion as part of standard of care and must also be evaluated by the

subject device. All clinical diagnostic standards used in the clinical study must follow standard clinical practice in the United States.

(E) Relevant demographic variables and baseline characteristics including medical history and neurological history. In addition, head injury characteristics, neurological assessments, and physical evidence of trauma must be provided for each subject. This information includes but is not limited to the following: Time since head injury, time from head injury to CT scan, time from head injury to blood draw, GCS score or equivalent, experience of loss of consciousness, presence of confusion, episodes of vomiting, post-traumatic amnesia characteristics, presence of post-traumatic seizures, drug or alcohol intoxication, mechanism of injury, acute intracranial lesion type, neurosurgical lesion, and cranial fracture.

(F) Each CT scan or other imaging result must be independently evaluated in a blinded manner by at least two board-certified radiologists to determine whether it is positive or negative as defined by the presence or absence of acute intracranial lesions. This independent review must be conducted without access to test results of the device. Prior to conducting the review, the criteria and procedures to be followed for scoring the images must be established, including the mechanism for determining consensus.

(G) All the clinical samples must be tested with the subject device blinded to the TBI status and the neurological-lesion-status of the subject.

(H) Details on how missing values in data are handled must be provided.

(I) For banked clinical samples, details on storage conditions and storage period must be provided. In addition, a specimen stability study must be conducted for the duration of storage to demonstrate integrity of archived clinical samples. The samples evaluated in the assay test development must not be used to establish the clinical validity of the assays.

(iii) Performance testing of device analytical specificity must include the most commonly reported concomitant medications present in specimens from the intended use population. Additionally, potential cross-reacting endogenous analytes must be evaluated at the highest concentration reported in specimens from the intended use population.

(iv) Expected/reference values generated by testing a statistically appropriate number of samples from apparently healthy normal individuals.

(2) The 21 CFR 809.10(a) and (b) compliant labeling must include the following limitations:

(i) A limiting statement that this device is not intended to be used a stand-alone device but as an adjunct to other clinical information to aid in the evaluation of patients who are being considered for standard of care neuroimaging.

(ii) A limiting statement that reads “A negative result is generally associated with the absence of acute intracranial lesions. An appropriate neuroimaging method is required for diagnosis of acute intracranial lesions.”

(iii) As applicable, a limiting statement that reads “This device is for use by laboratory professionals in a clinical laboratory setting.”

Dated: June 8, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2018–N–1862]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Endoscopic Electrosurgical Clip Cutting System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the endoscopic electrosurgical clip cutting system 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 endoscopic electrosurgical clip cutting system’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 June 14, 2018. The classification was applicable on December 22, 2017.

FOR FURTHER INFORMATION CONTACT: Purva Pandya, Center for Devices and Radiological Health, Food and Drug

Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G223, Silver Spring, MD 20993–0002, 240–402–9979, *Purva.Pandya@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the endoscopic electrosurgical clip cutting system 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 (21 U.S.C. 360(k) and part 807 (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. As a result, other device sponsors do not have to submit a De Novo request or PMA 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 April 11, 2016, Ovesco Endoscopy AG submitted a request for De Novo classification of the remOVE 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 has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.