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ELECTRONIC SUBMISSION
VIA DOCKET NO. FDA-2013-S-0610

Division of Dockets Management
U.S. Food and Drug Administration
Room 1061, HFA-305
5630 Fishers Lane
Rockville, MD 20852

PETITION FOR STAY OF ACTION AND FOR RECONSIDERATION

To Whom It May Concern:

On behalf of Nautilus Gloves LLC (Nautilus), the undersigned submits this petition for reconsideration of the December 12, 2023 rescission by the U.S. Food and Drug Administration (FDA or the Agency) of the substantial equivalence determination for the Nautilus Nitrile Exam Gloves (K210496) and for stay of the 510(k) rescission pending consideration of the request for reconsideration (Petition).

I. Decision Involved

This Petition challenges the December 12, 2023 rescission by FDA of the substantial equivalence determination for the Nautilus Nitrile Exam Gloves (K210496) (Rescission). FDA's stated basis for the Rescission was "information indicating that biocompatibility data contained in [the] submission is duplicative and identical to data from another unrelated submission." Nautilus requests reconsideration of the Rescission and a stay of the Rescission pending reconsideration, to permit Nautilus to amend the K210496 510(k) file with the correct biocompatibility data, which would replace data inadvertently submitted to FDA due to a clerical error.

II. Actions Requested

1. Pursuant to 21 C.F.R. § 10.33(b), Nautilus requests that the Commissioner of Food and Drugs (Commissioner) reconsider the Rescission, and instead permit Nautilus to amend the K210496 510(k) file with the correct In Vitro Cytotoxicity data for the Nautilus Nitrile Exam Gloves, thereby confirming the Agency's original finding of substantial equivalence.

2. Pursuant to 21 C.F.R. § 10.35(b), Nautilus requests that the Commissioner stay the Rescission pending reconsideration of the Rescission by the Commissioner.

III. Statement of Grounds

A. Background

On November 17, 2020, Boyuan Testing (BYT) initiated the biocompatibility testing process for the Nautilus Nitrile Exam Gloves pursuant to BYT's agreement with Nautilus' agent, Liaoning Hongen Medical Equipment Co., Ltd. (**Exhibit A;** Nov. 17, 2020 Testing Commission Agreement between Liaoning Hongen Medical Equipment Co., Ltd. and BYT, with Certified English Translation). Testing commenced on November 19, 2020, and BYT issued an In Vitro Cytotoxicity Test results report on January 8, 2021, Test Report No. BYT20Z0324880. Unaware that the BYT test report inadvertently contained data for a different product BYT had tested (not the Nautilus gloves), Nautilus included this test report in its February 16, 2021 510(k) submission and April 23, 2021 amended 510(k) submission. The "Test and control articles" table in the report states that the test article material is nylon, and the color is white, while the cover page correctly states that the gloves are nitrile and, as shown in the image on the last page, the Nautilus gloves are blue. These inconsistencies were not detected by Nautilus' regulatory consultant, who was responsible for accumulating the test reports and drafting the 510(k) premarket notification, Nautilus, or by the FDA reviewer during the 510(k) review.

On June 9, 2023, the Center for Devices and Radiological Health (CDRH) informed Nautilus that it intended to rescind Nautilus' 510(k) for the Nautilus Nitrile Exam Gloves (K210496). The basis for the rescission identified by CDRH in the Intent to Rescind letter was "due to the misconduct involving the submission of biocompatibility data that appears to be duplicated as it is identical to data from another unrelated submission" (emphasis added). On June 20, 2023, Nautilus timely requested a regulatory hearing under 21 C.F.R. Part 16.

In response to a request for a copy of the "unrelated submission" identified in the Intent to Rescind letter, CDRH provided the following additional explanation in an email dated June 26, 2023:

> To elaborate further on the duplicated data, the Nautilus Gloves 510(k), K210496, provided (pgs. 113-119 of 140 of the submission) an "In Vitro Cytotoxicity Test" reportedly conducted at Boyuan Testing with cell vitality results in Section 9.2 (pg. 118 of 140 of the submission). However, the cytotoxicity data in this table are identical to the cytotoxicity data from another 510(k) submission. This other submission is for a different device type (i.e., not a glove) that uses a different material, a different color, and was both conducted and submitted to FDA before K210496.[1]

On July 27, 2023, counsel for Nautilus requested a 30-day extension of time to provide its grounds in support of its request for a regulatory hearing while it conducted an investigation into the claims. CDRH did not respond to this request. Accordingly, without time to complete its investigation, on July 28, 2023, Nautilus timely submitted its Grounds Supporting Request for Regulatory Hearing and reiterated its request for a copy or actual details from the unrelated submission on fundamental due process grounds.

On August 4, 2023, the FDA Office of the Commissioner requested that CDRH respond to Nautilus' hearing request and July 28, 2023 Grounds Supporting Request for Regulatory Hearing to address whether the submissions raised a genuine and substantial issue of fact. On August 18, 2023, CDRH submitted its response, maintaining that Nautilus' hearing response should be denied under 21 C.F.R. § 16.26(a) due to lack of a genuine and substantial issue of fact. Nautilus responded to the CDRH's Opposition on September 5, 2023, stating (i) Nautilus was entitled to a hearing on due process grounds, and (ii) that it intended to present additional evidence at the hearing. In its August 18th opposition letter, CDRH revealed for the first time that the duplicate data was discovered by CDRH in June 2022, a year before the Intent to Rescind letter was issued.

Shortly after CDRH informed Nautilus that the data issue for K210496 510(k) was related to its In Vitro Cytotoxicity Test report, Nautilus contacted BYT to confirm the test report provided was correct. On September 10, 2023, BYT reported the results of its internal investigation findings to Nautilus, advising that a clerical error had taken place during a surge in testing orders during the COVID-19 pandemic, and that data from

[1] Email from LCDR Charles Chiang, CDRH (June 26, 2023).

another, unrelated test on a different product had inadvertently been included in the test report in place of Nautilus' In Vitro Cytotoxicity Test results.

> Unprompted, BYT provided a sworn statement with the following explanation:
>
> Customer Liaoning Hongen Medical Equipment Co., Ltd. provided feedback that the values in the test report NO: BYT20Z0324880 issued on January 8, 2021 were incorrect. After investigations by our company, there were indeed numerical errors. At the time, during the epidemic, our company's commissioned testing orders increased sharply. When the values were filled in, it was not filled in correctly due to the negligence of the staff. Presently the correct value commission by the customer at that time has been modified.

(**Exhibit B**; Sept. 5, 2023 Statement of Laboratory of Shenzhen Boyuan Testing Technology Co., with Certified English Translation). Critically, BYT identified and provided a copy of the actual test data from In Vitro Cytotoxicity testing of the Nautilus Nitrile Exam Gloves which should have been provided and submitted (**Exhibit C**; In Vitro Cytotoxicity Test, MTT Method, Final Report, Jan. 8, 2021). The correct test results, from testing of the Nautilus gloves, passed In Vitro Cytotoxicity testing in all respects.

On October 9, 2023, BYT re-confirmed to Nautilus that it relied on its data archive to confirm that the test data originally printed and included in the January 8, 2021 test report was incorrect, and that BYT then used the archived test data to issue the corrected report containing the actual, passing test results.

> Regarding the nitrile glove samples submitted for testing by Liaoning Hongen Medical Equipment Co., Ltd. on November 19, 2020, the test report of NO: BYT20Z0324880 was subsequently issued on January 8, 2021. The inspectors of our company retrieved the data archived at that time and checked with the test report data. There is indeed an inaccuracy …. Due to our company's error, we did not fill in the correct glove data in the test report. During the epidemic, our company's commissioned testing orders increased sharply. When the values were filled in, it was filled in with the incorrect values due to the negligence of the staff. Presently our company has entered the correct values on file at that time into the test report. We sincerely apologize for causing trouble to Liaoning Hongen Medical Equipment Co., Ltd.

(**Exhibit D**; Sept. 5, 2023 Revised Statement of Laboratory of Shenzhen Boyuan Testing Technology Co., with Certified English Translation).

Given the realization that there had been a simple clerical error, and that the actual results of the In Vitro Cytotoxicity testing were all passing, on October 11, 2023, counsel for Nautilus submitted a supplemental response to the CDRH's opposition to the hearing request, including the results of BYT's internal investigation, the sworn statements attesting that the results mix-up was a clerical error made by the laboratory, and the correct test results.

On November 1, 2023, CDRH responded to Nautilus' October 11th supplemental response. The November 1 response stated:

> Nautilus' supplemental response asserts that Nautilus' 510(K) submission (K210496) to the FDA included biocompatibility test result data from another company's unrelated product in the *In Vitro* Cytotoxicity test report for Nautilus' product. Under those facts, the data is invalid and cannot be the basis for a substantial equivalence determination. As such, Nautilus' supplemental response is consistent with the basis FDA articulated in its intent to rescind letter and therefore, there is no genuine issue of fact.

On November 28, 2023, the FDA Chief Scientist denied the hearing request and finalized the CDRH proposal to rescind K210496, directing CDRH to take the actions necessary to implement this decision. The denial concluded: "Whether the submission of duplicated and invalid information was the product of inadvertence is immaterial. The record establishes no dispute with respect to whether Nautilus submitted 'duplicated and invalid' data with its 510(k) notification. Therefore, there remain no material factual disputes warranting a hearing." Notably, this decision omits any reference to a finding of misconduct. On December 12, 2023, CDRH rescinded the K210496 clearance.

B. Argument

The Commissioner should reconsider and reverse the Rescission permitting Nautilus to amend the original 510(k) with the correct test data, which test data confirms CDRH's substantial equivalence decision for the Nautilus Nitrile Exam Gloves. The Commissioner should do so because the Recission was arbitrary, capricious, not in accordance with law, in excess of FDA's statutory authority, and completed without observance of process required by law.

Congress did not provide FDA with statutory authority to rescind 510(k) substantial equivalence determinations. Nor does the Rescission present any of the attributes that might allow FDA to exercise whatever inherent authority it may have. While administrative agencies have some inherent authority to correct prior decisions if

done in a timely fashion, an Agency may not rely on inherent reconsideration authority "when Congress has provided a mechanism capable of rectifying mistaken actions."[2] As held by the D.C. Circuit in *Ivy Sports Medicine*, in the case of 510(k) rescissions, Congress has provided a statutory mechanism to correct device classification errors via 21 C.F.R. § 360c(e), the device reclassification process.[3] Here, FDA has rescinded the Nautilus 510(k) clearance via a rescission letter, and has not sought reclassification through the statutory mechanism of notice-and-comment rulemaking. Accordingly, the Rescission is not in accordance with law, in excess of FDA's statutory authority, and was performed without the process required by law.

The Rescission is also invalid because it was, at least initially, based on alleged "misconduct" that has not been shown. As noted above, the June 9, 2023 Intent to Rescind Letter alleges "misconduct" but neither that letter nor any other evidence or information establishes any such misconduct by Nautilus, the sponsor. This is significant, because courts have acknowledged that an administrative agency may have more leeway when misconduct is involved. Specifically, *American Methyl* contemplates that an Agency may nevertheless use inherent authority, rather than statutory authority, "to revoke a waiver obtained through fraud, ex parte contacts, or other misconduct tainting the original record and thereby affecting the integrity of an agency's proceedings."[4] The D.C. Circuit in *Ivy Sports Medicine* defines misconduct as "some clear legal or ethical violation."[5] None of these conditions are met in connection with the K210496 510(k) rescission, however.

Although the June 9 Intent to Rescind letter cites "misconduct" as the basis for rescission of the Nautilus 510(k), Nautilus established in its October 11 supplemental response that the company did not engage in misconduct in the inadvertent submission of incorrect test results. As demonstrated through the sworn affidavit from BYT, the incorrect test result submission was the result of a clerical mix-up, and BYT provided a copy of the correct test report. This mix-up was neither a legal nor ethical violation constituting misconduct. And critically, FDA has not even alleged to the contrary in the Rescission.

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[2] *American Methyl Corp. v. EPA*, 749 F.2d 826, 835 (D.C. Cir. 1984).

[3] *Ivy Sports Med., LLC v. Burwell*, 767 F.3d 81, 86-87 (D.C. Cir. 2014).

[4] *American Methyl Corp.*, 749 F.2d at 834 n.51.

[5] *Ivy Sports Med.*, 767 F.3d at 88.

The incorrect test report included in the 510(k) plainly indicated the wrong test article, confirming no intention to deceive. Moreover, the error was missed by the company's FDA regulatory consultant and the FDA review team. Had the error been identified by FDA during the 510(k) review, as human errors and typographical issues often are during 510(k) reviews, the company could have simply corrected the submission prior to clearance (i.e., in response to a request for additional information). The fact that the error was identified post-clearance does not convert a human error into misconduct warranting 510(k) rescission.

Following submission of supplemental information establishing that the incorrect test result submission was inadvertent, CDRH abandoned its prior basis for rescission of "misconduct" and instead concluded that "[w]hether the submission of duplicated and invalid information was the product of inadvertence is immaterial." The final rescission was based solely on the mere fact of the duplicate data submission, even if not the result of misconduct. Therefore, the Agency cannot rely on the "misconduct" exception in *American Methyl* as a basis for its authority to rescind the 510(k).

Finally, *Ivy Sports Medicine* expressly notes that an Agency's inherent authority to revisit a prior decision must be "done in a timely fashion."[6] Here, FDA did not take timely action to correct its 510(k) substantial equivalence decision via the rescission. To the contrary, in CDRH's August 18th opposition to a hearing, CDRH revealed that the duplicate data was discovered by CDRH in June 2022, a year before the Intent to Rescind letter was issued.

Nautilus will suffer irreparable harm from the 510(k) rescission, which has the effect of invalidating the 510(k)-cleared status of devices distributed by the company in reliance on the 510(k). This harm is exacerbated by FDA's delay in taking action on the discovered error, by waiting one year after identification of the duplicate data before pursuing a rescission. Nautilus, therefore, requests that the Commissioner stay the 510(k) rescission pending the Commissioner's reconsideration of the 510(k) rescission.

IV. Conclusion

For the foregoing reasons, Nautilus requests that the Commissioner reconsider the Rescission decision pursuant to 21 C.F.R. § 10.33(b) and stay the Rescission pending the Commissioner's reconsideration of the decision pursuant to 21 C.F.R. § 10.35(b).

[6] *Id.* at 85.

Respectfully submitted,

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