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February 10, 2006

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

**Re: FDA Docket 2005P-0121/CCP 1;
Comments in Opposition to the Proposed Reclassification of External Bone Growth Stimulator ("BGS") Devices from Class III to Class II**

Dear Sir or Madam:

On behalf of the BGS Reclassification Opposition Group ("BGS Group"),¹ we submit the following comments in opposition to RS Medical's proposed down-classification of external bone growth stimulator ("BGS") devices from Class III to Class II. These comments will focus on the fundamental legal deficiencies in RS Medical's recent amendment to its petition² and will not review all of the arguments presented in our earlier response to the petition.³

FDA should deny the petition without panel review for the following reasons:

- RS Medical seeks to down-classify both CC and PEMF devices intended for non-unions and lumbar spinal fusions, but these different technologies and intended uses do not constitute a generic type of device. Indeed, RS Medical concedes this point by proposing different special controls for each BGS technology. FDA explicitly requested RS Medical to justify its proposed technical specifications and to provide the range necessary to ensure a safe and effective signal.⁴ RS Medical refuses to do so.⁵ Hence, RS Medical has "inadequately characterize[d]"

¹ The BGS Group is comprised of the leaders in this device field—dj Orthopedics, Inc., EBI, L.P., and Orthofix, Inc.

² RS Medical, Amendment to RS Medical's Petition for the Reclassification of the Non-invasive Bone Growth Stimulator, FDA Docket 2005P-0121 (Nov. 30, 2005) ["RS Medical Amendment"].

³ King & Spalding LLP, Comments in Opposition to the Reclassification of External Bone Growth Stimulators, FDA Docket 2005P-0121/CCP 1 (Aug. 17, 2005) ["BGS Group Comments"].

⁴ FDA Letter to RS Medical (Aug. 12, 2005) ["FDA Letter"] at 3.

⁵ RS Medical refuses to define the technical specifications purportedly because "enough is known about the safety and effectiveness of these devices to make the setting of technical specifications unnecessary." RS Medical Amendment at 25. The studies cited by RS Medical, however, do not constitute adequate valid scientific evidence for down-classification. RS Medical fails to justify the pooling and comparison of these studies, which use inconsistent or unknown study parameters. The available literature also demonstrates that the basic mechanisms of action for BGS devices are unknown.

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the devices for reclassification,⁶ and the petition should be denied.

- Contrary to FDA regulations, RS Medical fails to include all unfavorable data in its petition.⁷ Numerous studies demonstrate that ostensibly minor changes to BGS devices can adversely impact safety and effectiveness⁸ and that the basic mechanisms of action for these devices remain unknown.⁹ These studies show that BGS devices are ill suited for a comparative determination of “substantial equivalence” and that insufficient evidence exists to demonstrate that the proposed special controls are adequate. FDA regulations require the inclusion of these unfavorable data. Consequently, the petition should be denied.
- Contrary to FDA’s explicit request,¹⁰ RS Medical provides no scientific rationale for consolidating or comparing studies with unknown or inconsistent study protocols and parameters.¹¹ Thus, the petitioner presents insufficient valid scientific evidence to support reclassification and the petition should be denied.
- Only PMA clinical trials and premarket review of manufacturing will ensure that BGS devices are safe and effective. Without validation, RS Medical asserts that designing BGS devices, which are “virtually identical” to the PMA-approved devices, would be “normally accomplished.”¹² RS Medical, however, fails to replicate the PMA-approved waveforms and to identify the necessary technical specifications for BGS devices, as requested by FDA. Even if a new manufacturer could replicate the PMA-approved devices, RS Medical provides no evidence that PMA controls are unnecessary and that the proposed special controls would be sufficient to reasonably assure the accomplishment of this task. Hence, RS Medical fails to disprove the necessity of PMA review and to prove the adequacy of the proposed special controls. Consequently, the petition should be denied.

RS Medical’s amended petition remains legally and scientifically deficient and thus unworthy of panel review. As the petitioner for down-classification, RS Medical bears the burden of proof, “regardless of whether those opposing reclassification can or do submit evidence showing that reclassification is not appropriate.”¹³ RS Medical has wholly failed this burden. Therefore, FDA

⁶ *Contact Lens Mfrs. Ass’n v. FDA*, 766 F.2d 592, 600 (D.C. Cir. 1985) (affirming FDA’s denial of the reclassification petition for rigid gas permeable (“RGP”) contact lenses), *cert. denied*, 474 U.S. 1062 (1986).

⁷ RS Medical Amendment at 6-10.

⁸ See BGS Group Comments at 19-24.

⁹ See *id.* at 9-12.

¹⁰ FDA Letter at 1.

¹¹ “In RS Medical’s opinion, there is no need for additional evaluations of these studies, and there is certainly no reason to eliminate them from consideration” RS Medical Amendment at 6.

¹² *Id.* at 25, 27.

¹³ *Reclassification of Daily Wear Spherical Contact Lenses Consisting of Rigid Gas Permeable Plastic Materials; Withdrawal of Proposed Rule*, 48 Fed. Reg. 56,778, 56,783 (Dec. 23, 1983) [“RGP Contact Lens Notice”]. “The

should reject the proposed down-classification and sustain the successful PMA review of BGS devices.

I. RS Medical fails to identify a generic type of device for reclassification.

The reclassification petitioner must identify a “generic type of device” for reclassification.¹⁴ Unable to characterize a “generic” BGS device, RS Medical attempts to shift the burden to FDA: “In the companion final rule, FDA is finalizing the names and identification of this device type.”¹⁵ RS Medical originally proposed the down-classification of CC, PEMF, and CMF devices.¹⁶ Upon admitting the lack of valid scientific evidence supporting the reclassification of CMF devices, RS Medical cavalierly eliminated this technology from its proposal.¹⁷ The CC and PEMF devices proposed by the petitioner do not constitute a generic type of device for reclassification. RS Medical has neither replicated the waveforms of PMA-approved devices nor characterized a range of technical specifications with proven safety and effectiveness. Absent an identification of a generic type of BGS device, there is no regulatory basis for reclassification.¹⁸

A “generic type of device” is a “grouping of devices that do not differ significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness, and for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness.”¹⁹ By contrast, CC and PEMF devices differ substantially in their mechanisms of action, waveforms, dosimetries, designs, and intended uses in ways that directly impact device safety and effectiveness and therefore require individualized, not generic, special controls. Even within a specific BGS technology, significant differences remain.²⁰

In the preamble to the device classification regulation, FDA specifically recognized that “[b]y definition, all devices within a generic type present the same or very similar risks to health. . . . If devices thought to be within the same generic type present different risks, it is likely that

opponents of reclassification are not required to provide any evidence to establish that reclassification is inappropriate.” *Id.* at 56,792.

¹⁴ 21 C.F.R. § 860.3(i).

¹⁵ Revised RS Medical Guidance (redlined version), *in* RS Medical Amendment at 102.

¹⁶ RS Medical, Reclassification Petition for the Non-invasive Bone Growth Stimulator under Section 513(e) of the FDCA, FDA Docket 2005P-0121 (filed Feb. 9, 2005) [“RS Medical Petition”] at 3-5.

¹⁷ RS Medical Amendment at 10.

¹⁸ *See Contact Lens Mfrs. Ass’n*, 766 F.2d at 600-601 (“Independently sufficient and far more persuasive is the FDA’s determination that all reclassification proposals to date ‘inadequately characterize’ the class of RGP lenses. . . . [T]hus, at least for the present, the premarket approval process is unavoidable.”)

¹⁹ 21 C.F.R. § 860.3(i).

²⁰ For example, PEMF devices differ in their specific signals, dosimetries, and designs. *See* BGS Group Comments at 9-14, 20-24. Since there is only one FDA-approved CC device, it also would be improper for RS Medical to seek the down-classification of only CC devices. By definition, only a “grouping of devices” can constitute a “generic type of device.” 21 C.F.R. § 860.3(i).

the devices are not really of the same generic type.”²¹ In FDA’s Draft Guidance, the Agency concluded that the various BGS technologies pose different health risks that necessitate technology-specific special controls.²² Indeed, RS Medical concedes in its proposed guidance document that CC and PEMF devices pose different safety risks and therefore require different preclinical testing.²³ These technology-specific safety issues further underscore that the CC and PEMF devices are not of the same generic type.

RS Medical has failed to adequately define the PMA-approved devices, let alone a generic type of BGS device. RS Medical conducted testing on several used and expired BGS devices²⁴ in an attempt to demonstrate that the PMA-approved waveforms could be readily defined and replicated. RS Medical limited its testing to select models and completely ignored a BGS device intended for spinal fusion.²⁵ Even after testing several BGS devices, RS Medical was unable to replicate the waveforms of proven safety and effectiveness, or to identify the range of technical specifications that are necessary for a safe and effective signal, as requested by FDA.²⁶ Yet, it is this type of ad hoc testing that RS Medical purports would reasonably assure the safety and effectiveness of future BGS devices. Even if the specifications of the PMA-approved devices could be accurately and fully characterized, compelling new devices to meet such exact specifications is inconsistent with the substantial equivalence standard, simply highlighting the absence of a generic type of BGS device and the inappropriateness of Class II designation.²⁷

RS Medical implicitly admits that the BGS devices proposed for reclassification are not substantially equivalent devices within the same generic type. If they were substantially equivalent, then the reclassification of one BGS technology would have reclassified the other BGS technologies because “[t]he reclassification of any device within a generic type of device causes the reclassification of all substantially equivalent devices within that generic type.”²⁸ In other words, if CC and PEMF devices were substantially equivalent to each other, then RS

²¹ *Medical Devices: Classification Procedures*, 43 Fed. Reg. 32,988, 32,992 (July 28, 1978).

²² The FDA Draft Guidance states that “[d]ifferent safety concerns have been identified in the literature for each of the modalities for BGS devices Therefore, safety testing should be performed to address the safety issues related to the specific modality involved.” *Guidance Document for Industry and CDRH Staff for the Preparation of Investigational Device Exemptions and Premarket Approval Applications for Bone Growth Stimulator Devices* (Mar. 18, 1998) [“FDA Draft BGS Guidance”].

²³ Revised RS Medical Guidance (redlined version), in RS Medical Amendment at 107-110.

²⁴ We note that the expired devices would have required disassembly in order to test them.

²⁵ Although proposing the down-classification of the Orthofix Spinal-Stim device, RS Medical did not test, replicate, or accurately identify the technical specifications for this device. RS Medical tested the Orthofix Physio-Stim Model 202L but failed to demonstrate that these test results were applicable to other models.

²⁶ FDA requested a “rationale to justify how the proposed technical specifications are sufficient to validate an effective clinical treatment signal” and the “range of technical specification . . . necessary to ensure a clinically effective treatment signal/dose.” FDA Letter at 3.

²⁷ RS Medical has not demonstrated that the proposed special controls would be adequate to determine whether a new BGS device is identical to a PMA-approved BGS device. See *infra* Part IV.

²⁸ 21 C.F.R. § 860.120(b).

Medical would not have specified each technology's distinctive risks, special controls, and relevant studies in the reclassification petition. Moreover, RS Medical would not have abandoned reclassification of the CMF devices because of a lack of valid scientific evidence on this specific technology,²⁹ but rather would have offered the CC and PEMF literature to support the reclassification of CMF devices.

II. RS Medical fails to provide all representative data that are unfavorable to the proposed down-classification.

A reclassification petition must include all "representative data and information known by the petitioner that are unfavorable to the petitioner's position."³⁰ RS Medical dismisses FDA's request for these data,³¹ insisting instead that all preclinical and clinical studies showing "unsafe or ineffective output parameters . . . are not pertinent to the reclassification," unless they specifically involve a marketed BGS device named in RS Medical's petition.³² Contrary to RS Medical's assertion, these data are unfavorable and should have been included in the petition.

The scientific literature shows that: (1) seemingly minor changes to BGS devices, e.g., to their waveforms, dosimetry, etc., may render a device ineffective or unsafe³³ and (2) the basic mechanisms of action for these devices remain unknown.³⁴ These studies are unfavorable to RS Medical's petition because they demonstrate that BGS devices require PMA-type controls—rigorous preclinical and clinical testing and manufacturing oversight—to assure their safety and effectiveness. Contrary to the precision required by BGS devices, the substantial equivalence paradigm would permit the clearance of devices that are similar, but not necessarily identical, to devices with proven safety and effectiveness. Studies show that the sensitivity and specificity of BGS devices make them ill suited for marketing clearance based on comparative determinations. Furthermore, these studies illustrate that significant questions remain about the key performance parameters of BGS devices, thereby corroborating that insufficient information exists to support down-classification.

RS Medical reluctantly admits that a study by Barker et al. (1984),³⁵ which found that a PEMF treatment did not enhance the repair of non-unions as compared to the control, "might be construed as unfavorable."³⁶ RS Medical incorrectly claims that this study did not identify the

²⁹ RS Medical Amendment at 10.

³⁰ 21 C.F.R. § 860.123(a)(7) (emphasis added).

³¹ FDA Letter at 1.

³² RS Medical Amendment at 7 (emphasis added). This excuse directly contradicts the petitioner's recognition that a BGS device, which was different from a PMA-approved device, could be found substantially equivalent pursuant to the proposed down-classification. *Id.* at 27-28.

³³ See BGS Group Comments at 19-23.

³⁴ See *id.* at 9-12.

³⁵ A.T. Barker et al., *Pulsed Magnetic Field Therapy for Tibial Non-Union*, 1 LANCET 993-96 (1984).

³⁶ RS Medical Amendment at 10.

device used³⁷ and dismisses the findings because of the study's size.³⁸ In any event, the regulatory requirement is to provide all representative unfavorable data known to the petitioner and does not permit exclusion of unfavorable data merely because they were not part of a well-controlled investigation.³⁹

III. RS Medical fails to provide sufficient valid scientific evidence to support the proposed down-classification.

A reclassification petition must provide sufficient valid scientific evidence to demonstrate that the proposed special controls would reasonably assure safety and effectiveness.⁴⁰ RS Medical blatantly refuses⁴¹ FDA's request for a "rationale for consolidating the provided literature studies as scientific evidence considering the studies' inconsistencies" and "an analysis of these disparate study parameters and their affect on the validity of the scientific evidence."⁴² RS Medical proffers a specious excuse: "Seeing similar results from somewhat different study approaches reinforces, rather than calling into question, the conclusion that the Non-Invasive Bone Growth Stimulator can be a safe and effective type of device."⁴³ This excuse clearly contradicts the basic principles of clinical study design and analysis.⁴⁴ Absent the rationale and analysis requested by FDA, there is insufficient valid scientific evidence to support reclassification.⁴⁵

There is no scientific rationale for comparing or aggregating data from studies with unknown waveforms and inconsistent study protocols. None of the studies cited by RS Medical adequately describes the waveforms used. Without a clear characterization of these waveforms, RS Medical has no basis for comparing the studies or concluding that the proposed special controls would reasonably assure BGS safety and effectiveness. Although FDA may consider several types of valid scientific evidence, the Agency may not consider "[i]solated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and

³⁷ The study used BGS devices that produced 1.5 mT peak, 5 ms burst waveforms, repeated at 15 Hz. For the waveform specifications and the "full technical details of the stimulator used," the article provides citations to Barker and Lunt (1983) and Barker (1981). Barker et al. (1984) at 994, 996.

³⁸ More than half of the studies cited by RS Medical in support of reclassification involved similarly small patient populations. See BGS Group Comments at 29.

³⁹ 21 C.F.R. § 860.7(c)(2). In fact, FDA may consider this type of evidence for the purposes of "identifying a device the safety and effectiveness of which is questionable."

⁴⁰ See Federal Food, Drug, and Cosmetic Act § 513(a)(1)(B); 21 C.F.R. § 860.7(c)(2).

⁴¹ "In RS Medical's opinion, there is no need for additional evaluations of these studies, and there is certainly no reason to eliminate them from consideration . . ." RS Medical Amendment at 6.

⁴² FDA Letter at 1.

⁴³ RS Medical Amendment at 4.

⁴⁴ See ICH Harmonised Tripartite Guideline, *Statistical Principles for Clinical Trials: E9* (Feb. 5, 1998); CURTIS L. MEINERT, CLINICAL TRIALS: DESIGN, CONDUCT, AND ANALYSIS 276-77 (Oxford Univ. Press 1986).

⁴⁵ For a complete critique of the cited studies, please refer to the BGS Group Comments and the additional technical comments on RS Medical's amendment.

unsubstantiated opinions,” except for the purposes of “identifying a device the safety and effectiveness of which is questionable.”⁴⁶

In rejecting the down-classification of rigid gas permeable (“RGP”) contact lenses, FDA concluded that the literature in support of reclassification “requires detailed characterization of the lens or lenses from which the evidence is drawn and the lenses to which the characterization applies.”⁴⁷ Otherwise, there was “no basis for extrapolation of evidence of the safety and effectiveness from one lens to any other.”⁴⁸ The D.C. Circuit agreed that “all reclassification proposals to date ‘inadequately characterize’ the class of RGP lenses.”⁴⁹ Thus, “even if the available evidence demonstrates the safety and effectiveness of lenses already on the market, this evidence cannot be taken as proof that any RGP lens a manufacturer might create will meet the statutory requirements.”⁵⁰ Here, the scant information on the BGS waveforms used in the cited studies provides no basis for extrapolating these studies to a poorly defined class of BGS devices.

There is no scientific rationale for comparing or aggregating data from studies with significantly different study protocols.⁵¹ RS Medical cites studies with various inclusion/exclusion criteria, treatment regimens, durations-of-use, timeframes for follow-up, and definitions of clinical success.⁵² For example, to support the down-classification of CC devices, RS Medical relies principally on PEMF studies, which have limited, if any, applicability to CC devices. RS Medical also relies inappropriately on non-union studies to support the down-classification of devices that apply electrical signals directly to the human spine. Most of the cited studies also lack data on BGS safety and use insufficient patient populations for analysis.

IV. RS Medical fails to demonstrate that PMA review is unnecessary and that the proposed special controls would reasonably assure BGS safety and effectiveness.

Only PMA clinical trials and premarket review of manufacturing will reasonably assure BGS safety and effectiveness. The safety and effectiveness of BGS devices “is a function of the complex interrelationship of material, design, and manufacture.”⁵³ As discussed above, these devices are unsuited for comparative determinations of substantial equivalence because ostensibly minor changes to BGS devices can result in ineffective or unsafe signals.⁵⁴ Under 510(k) review, the “piggybacking” of predicate devices would encourage a cascade of seemingly

⁴⁶ 21 C.F.R. § 860.7(c)(2) (emphasis added).

⁴⁷ RGP Contact Lens Notice, 48 Fed. Reg. at 56,789 (emphasis added).

⁴⁸ *Id.*

⁴⁹ *Contact Lens Mfrs. Ass’n*, 766 F.2d at 600.

⁵⁰ *Id.* at 600-601 (emphasis added).

⁵¹ See ICH Harmonised Tripartite Guideline, *Statistical Principles for Clinical Trials: E9* (Feb. 5, 1998); CURTIS L. MEINERT, *CLINICAL TRIALS: DESIGN, CONDUCT, AND ANALYSIS* 276-77 (Oxford Univ. Press 1986).

⁵² See BGS Group Comments at 28-29.

⁵³ RGP Contact Lens Notice, 48 Fed. Reg. at 56,781.

⁵⁴ See BGS Group Comments at 19-23.

similar, but ultimately unproven, BGS devices to flood the market. Furthermore, insufficient information exists to demonstrate the adequacy of RS Medical's proposed special controls. There is no well-defined BGS predicate device, given the open questions about the key parameters of these devices.⁵⁵ Moreover, the petitioner relies on seriously flawed studies that have unknown and inconsistent study parameters.

PMA clinical data are necessary to reasonably assure BGS safety and effectiveness. The "vast majority" of 510(k) notifications, however, do not require clinical data.⁵⁶ Even if FDA requests clinical data for a 510(k), the Agency is limited to "information that is necessary to making substantial equivalence determinations" and may not request clinical data demonstrating that the device is safe and effective.⁵⁷ FDA recognized the limits of 510(k) review during the proposed down-classification of RGP contact lenses. The Agency concluded:

Where, as in this case, the type and amount of information that would be required to show substantial equivalence in terms of safety and effectiveness would approximate the type and amount of information required to obtain approval of a PMA for a device, reclassification of the device based on reliance on the process under section 510(k) of the act would not be justified.⁵⁸

Upholding the Agency's refusal to down-classify the RGP lenses, the D.C. Circuit remarked on the practical problems created by turning a 510(k) notification into a quasi-PMA. Reviewing PMA-type information on a "comparison basis" would prove "difficult and constraining."⁵⁹ Also, "the exacting character of the comparisons involved might discourage innovation by requiring the manufacturer of a new RGP lens to demonstrate 'substantial equivalence' almost to the point of patent infringement."⁶⁰

Furthermore, PMA review permits a crucial premarketing assessment of BGS device manufacturing. Even with complete characterizations of the various BGS technical specifications—which are notably absent from RS Medical's proposed reclassification—a BGS device must consistently produce a safe and effective signal within a proven range. Since even slight changes to a BGS waveform may render a signal ineffective, it is imperative that a

⁵⁵ *See id.* at 9-12.

⁵⁶ "The vast majority of these [510(k)-cleared] devices are found to be substantially equivalent to a predicate device [21 CFR 807.92(a)(3)] based upon: 1) a complete design description of the device, and 2) data from preclinical testing (bench and/or animal studies). New clinical data are not required in most of these circumstances." *Draft Guidance on Evidence Models for the Least Burdensome Means to Market* (September 1999). The House Report for the Safe Medical Devices Act estimated that the Agency required clinical data in less than 10% of all 510(k) notifications. H.R. REP. NO. 101-808, Safe Medical Devices Act of 1990 (Oct. 5, 1990), at 25.

⁵⁷ FDA must "consider the least burdensome means of demonstrating substantial equivalence." Federal Food, Drug, and Cosmetic Act § 513(i)(1); *see* H.R. REP. NO. 105-307, at 24 (1997).

⁵⁸ RGP Contact Lens Notice, 43 Fed. Reg. at 56,790.

⁵⁹ *Contact Lens Mfrs. Ass'n*, 766 F.2d at 601 (internal citations omitted).

⁶⁰ *Id.*

company reliably manufacture BGS devices within the specific tolerances for each waveform parameter. Only PMA review authorizes the necessary premarket evaluation of these manufacturing processes.

In its letter to RS Medical, FDA requested a “rationale to justify how the proposed technical specifications are sufficient to validate an effective clinical treatment signal” and the “range of technical specification . . . necessary to ensure a clinically effective treatment signal/dose.”⁶¹ RS Medical, however, fails to replicate the PMA-approved waveforms, to justify the proposed specifications, and to define an appropriate range of specifications.⁶² RS Medical’s inability to delineate these fundamental benchmarks of BGS safety and effectiveness belies the company’s suggestion that defining and reproducing these benchmarks would be “challenging but normally accomplished.”⁶³ RS Medical also has not provided sufficient valid scientific evidence to prove that “enough is known about the safety and effectiveness of these devices to make the setting of technical specifications unnecessary.”⁶⁴

In its amendment, RS Medical proposes cursory warning language to address the potential risks of carcinogenicity, mutagenicity, cell toxicity, teratological effects, thermal burns, and complications for patients with electrical implants or fixation devices. These suggestions are dangerously inadequate. We provide a complete critique of the proposed special controls in our other comments on the down-classification.⁶⁵

V. Conclusion

Throughout its bid for reclassification, RS Medical has sought to evade FDA’s reclassification and premarket requirements. RS Medical petitions for reclassification while simultaneously offering to abandon the petition in exchange for distribution agreements with current BGS manufacturers.⁶⁶ RS Medical attempts to use reclassification to avoid both PMA and 510(k) requirements for its unmarketed device.⁶⁷ RS Medical does not characterize the BGS devices for reclassification, arguing instead that the device’s technical specifications are unnecessary and that FDA will define the devices for reclassification. Rather than addressing the “unfavorable” data, RS Medical disputes the plain meaning of this regulatory term. RS Medical does not justify its consolidation and comparison of studies with unknown and inconsistent study parameters, but rather summarily concludes that such analysis is unnecessary. Despite FDA’s requests, RS Medical continues to flout the legal standards for reclassification and the

⁶¹ FDA Letter at 3.

⁶² See *supra* note 25.

⁶³ RS Medical Amendment at 25.

⁶⁴ *Id.*

⁶⁵ Please refer to BGS Group Comments at 25-26 and the additional technical comments.

⁶⁶ Orthofix Record of Conversation with RS Medical employee (Aug. 4, 2005). RS Medical also sought a similar arrangement with EBI.

⁶⁷ RS Medical proposed that the reclassification petition would exempt the company from any 510(k) notification for its uncleared BGS device. RS Medical Petition at 88-89.

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fundamental principles of scientific analysis. Hence, the petition remains defective and RS Medical has failed its burden of proof.

FDA should not countenance this attempted end-run of the regulations. To permit this deficient petition to move forward would undercut the legal and scientific standards governing reclassifications. RS Medical has not proven that the PMA review of BGS devices is unnecessary and that its proposed special controls would reasonably assure safety and effectiveness. We urge FDA to refuse panel review and reject the proposed down-classification of BGS devices.

Respectfully submitted,



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