



B&Medi Co., Ltd.
Taesu Kwon, CEO
56-33, Chukhang-daero 296Beon-gil, Jung-gu 8/18/22
Incheon, Incheon 22339
KOREA, SOUTH

Re: K210797
Trade/Device Name: Bio-MEM Ti Reinforced Membrane
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPK
Dated: March 11, 2021
Received: March 16, 2021

Dear Taesu Kwon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew Steen
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K210797

Device Name

Bio-MEM Ti Reinforced membrane

Indications for Use (Describe)

Bio-MEM Ti Reinforced membranes are an implantable temporary non-resorbable device (membrane) for use as a spacer creation barrier in the treatment of local defects in the oral cavity in conjunction with tissue regeneration or augmentation. Bio-MEM Ti Reinforced membranes are intended to be submerged and clinically implanted more than 30 days and no longer than 6 months.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

1. Submitter

Name: B&Medi Co., Ltd.
Address: 56-33, Chukhang-daero 296Beong-gil, Jung-gu,
Incheon, 22339, Korea
Tel/ Fax: Tel: 82-2-6295-0085, Fax : 82-2-6295-0085
Contact: Taesu Kwon/CEO, Email : cms@bnmedi.com
Date of Submission: Aug 18, 2022

2. Device

Trade/Device Name: Bio-MEM Ti Reinforced Membrane
Common name: Non-Resorbable Barrier Membrane
Regulation Number: 21 CFR 872. 3930
Regulation name: Barrier, Synthetic, Intraoral
Regulation Class: II
Product Code : NPK

3. Predicate Device

Primary Predicate Device

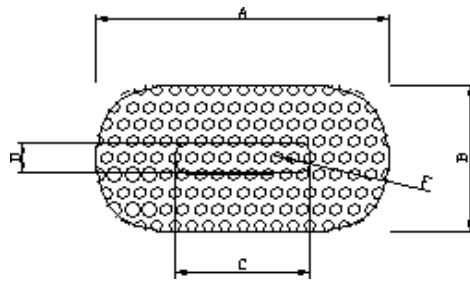
: Neoss Ti Reinforced Membrane (K143327, Neoss, Ltd)

Reference Predicate Device

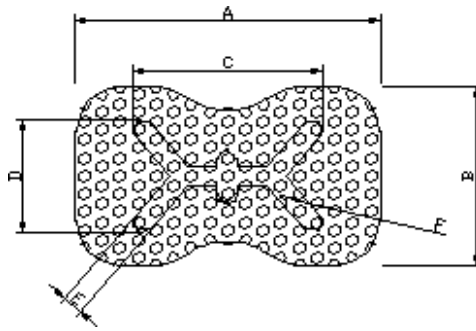
: Cytoplast Regentex™ Titanium 250 (K972278 ; Osteogenics Biomedical Co.,Ltd)

4. Description

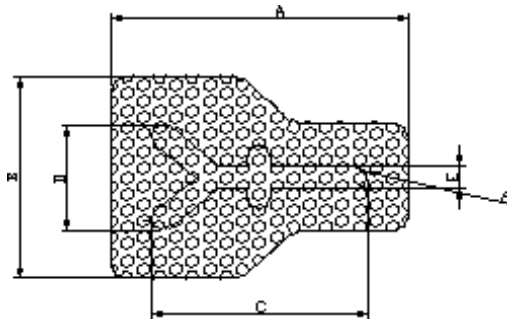
Bio-MEM Ti Reinforced membranes are non-resorbable membranes available as Ti-reinforced configured of a highly shapeable Ti (Reinforced only) enveloped by an embossed polytetrafluoroethylene (PTFE) membrane. Extensive documentation demonstrates tissue compatibility of PTFE. **Bio-MEM** Ti Reinforced membranes are designed to avoid ingrowth of gingival soft tissue into bony defects, in order to facilitate the neovascularization and bone formation during the repair process of the defect. **Bio-MEM** Ti Reinforced membranes are provided STERILE and in different anatomical shapes and sizes. The titanium reinforcement is intended for space creating and shape-maintaining which minimize movements and subsequent exposure during the regenerative healing.



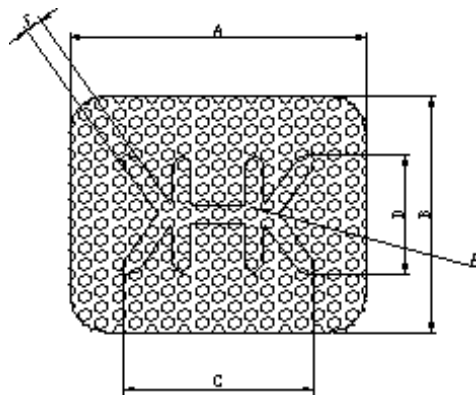
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1	PM1224A	24.0	12.0	11.0	2.5	0.25



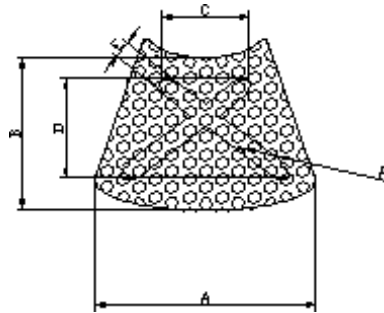
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2	PM1424A	24.0	14.0	14.84	8.89	1.59	0.25



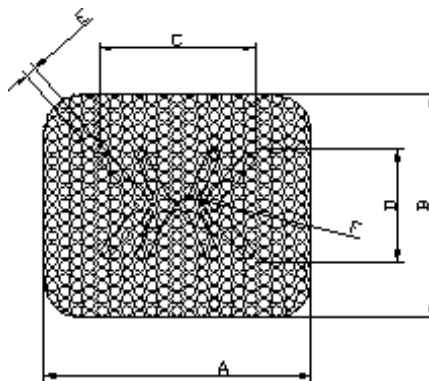
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3	PM1725A	25.0	17.0	18.36	8.83	2.0	0.25



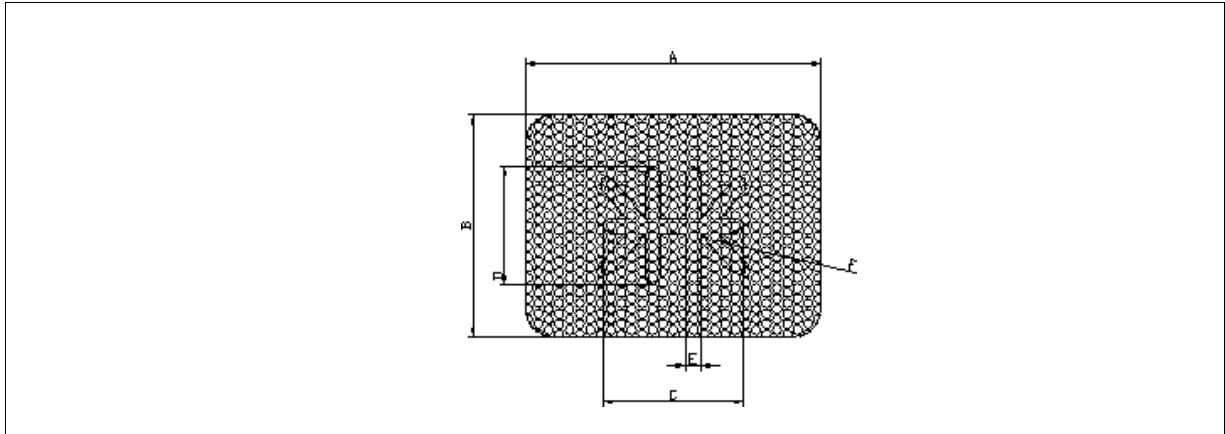
No	Model	A(mm)	B(mm)	C(mm)	D(mm)	E(mm)	F(Thickness)
4	PM2025A	20.0	25.0	15.99	10.0	1.5	0.25



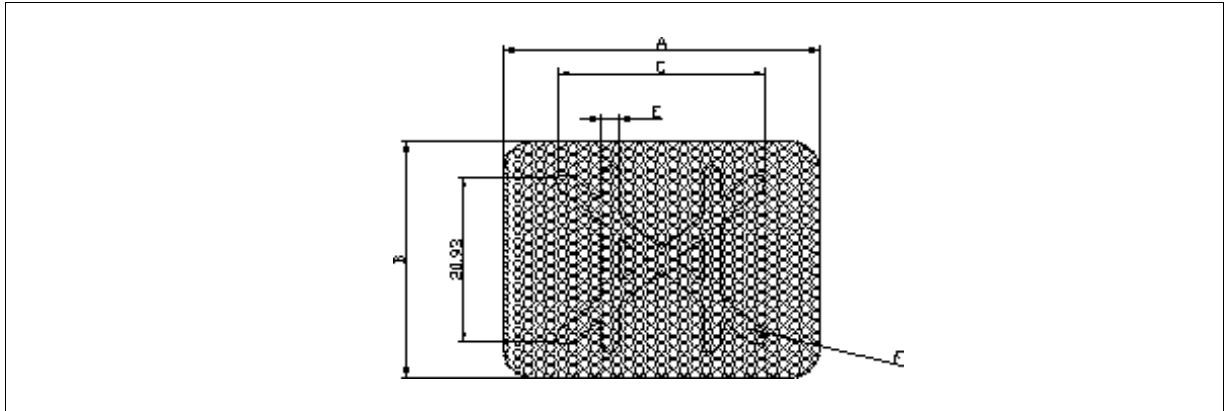
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5	PM1319A	19.0	13.0	7.49	8.44	1.5	0.25
6	PM1318A	18.0	13.0	7.91	7.66	1.5	0.25



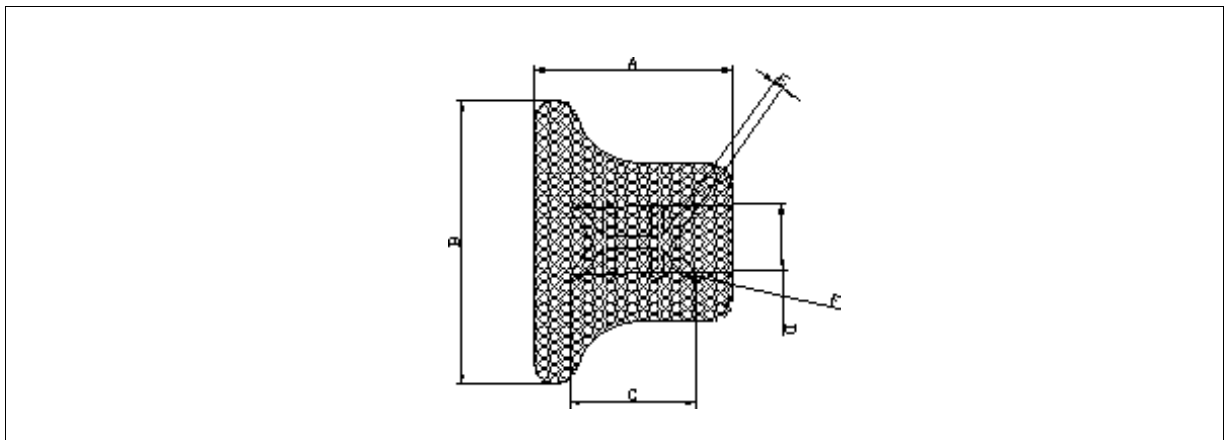
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7	PM2530A	30.0	25.0	17.57	12.65	1.3	0.25



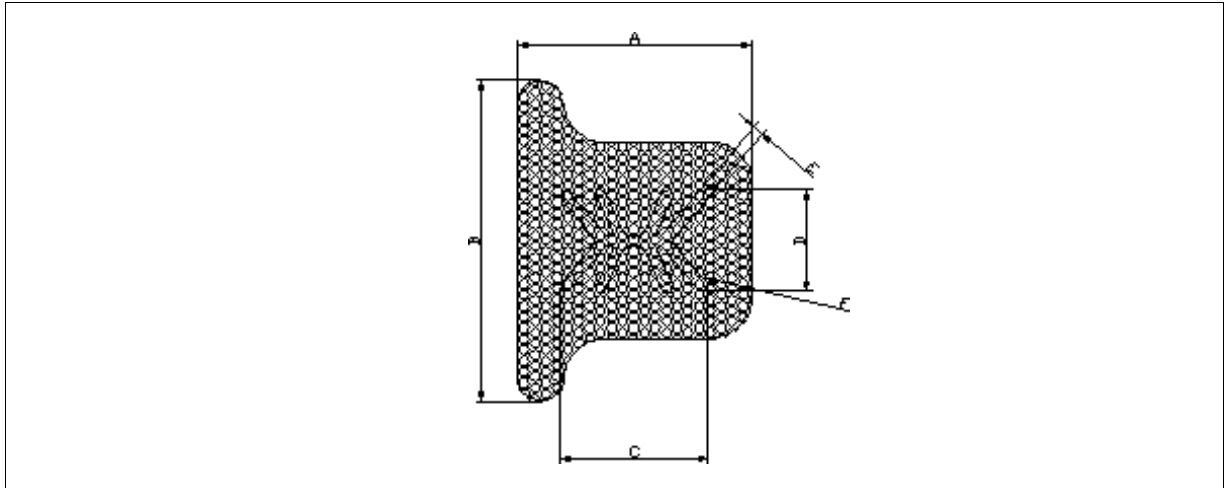
No	Model	A(mm)	B(mm)	C(mm)	D(mm)	E(mm)	F(Thickness)
8	PM3040S2	30.0	40.0	22.0	18.0	2.0	0.25
9	PM3040SA	30.0	40.0	19.0	16.0	2.0	0.25



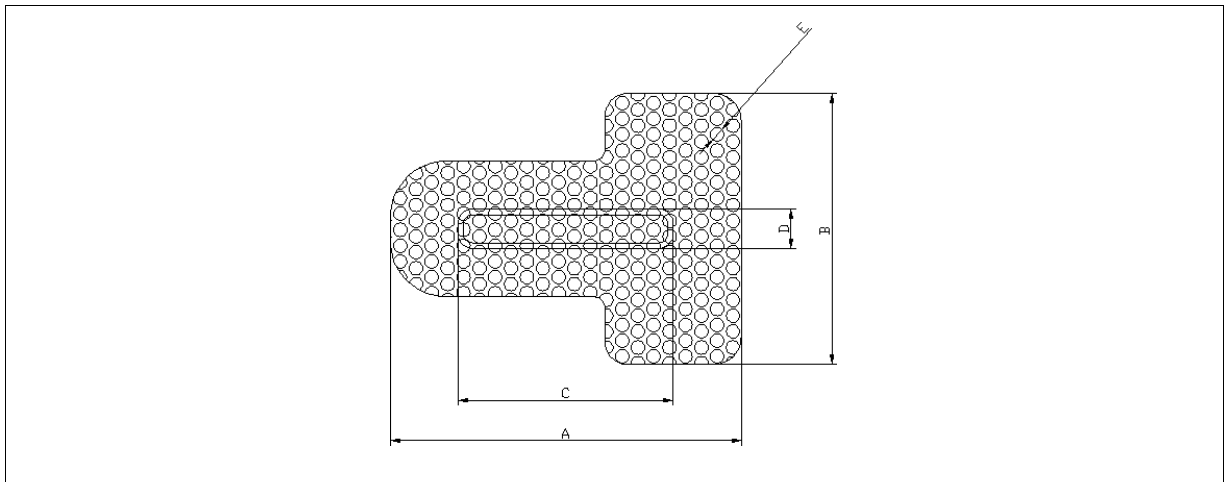
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10	PM3040A	40.0	30.0	26	20.93	2.22	0.25



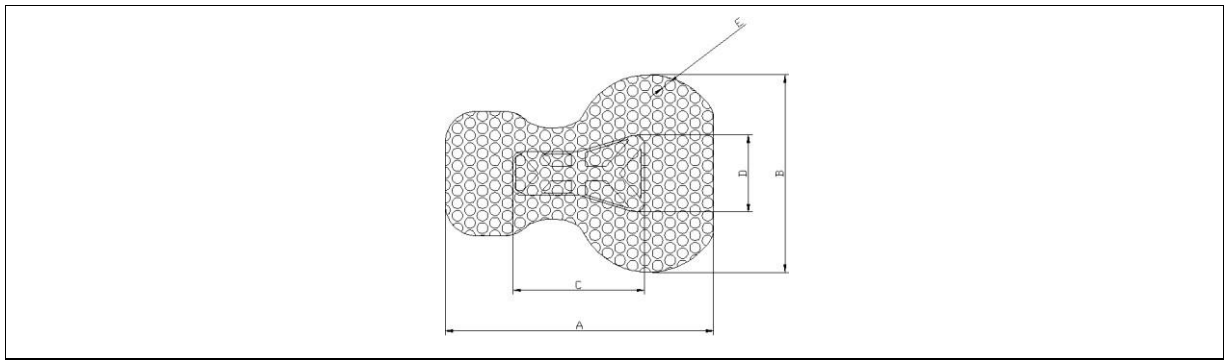
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11	PM2536A	25.0	36.0	15.99	10.13	1.5	0.25



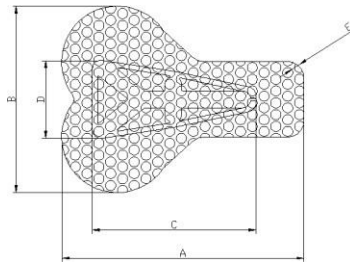
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12	PM3041A	30.0	41.0	18.97	12.92	1.4	0.25



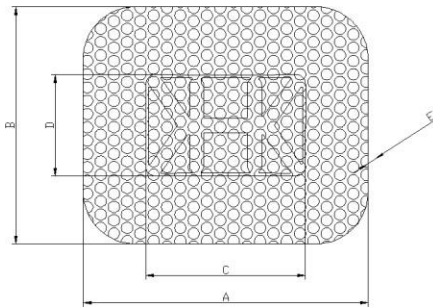
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13	PMB2431	31.0	24.0	19.0	3.5	0.25



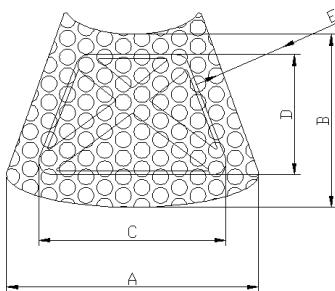
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14	PMB2030	30.0	20.0	14.7	8.6	0.25



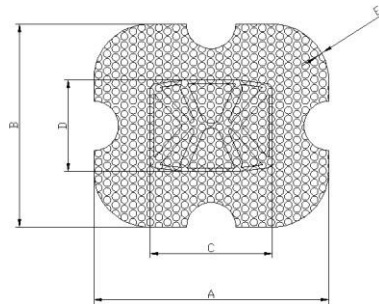
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15	PMB2228	28.0	22.0	19.3	9.2	0.25



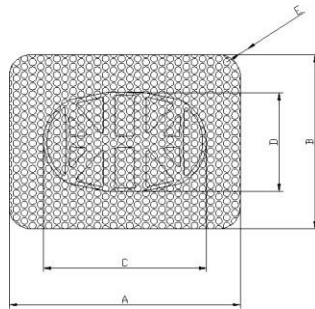
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16	PMB2530S	30.0	25.0	16.8	10.6	0.25



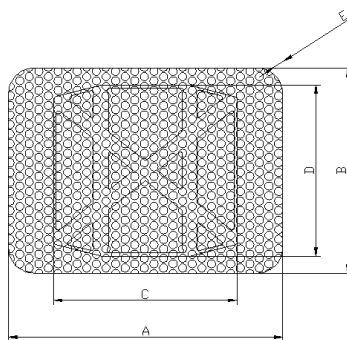
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17	PMB1319	19.0	13.0	14.0	9.0	0.25
18	PMB1318	18.0	13.0	13.4	8.5	0.25



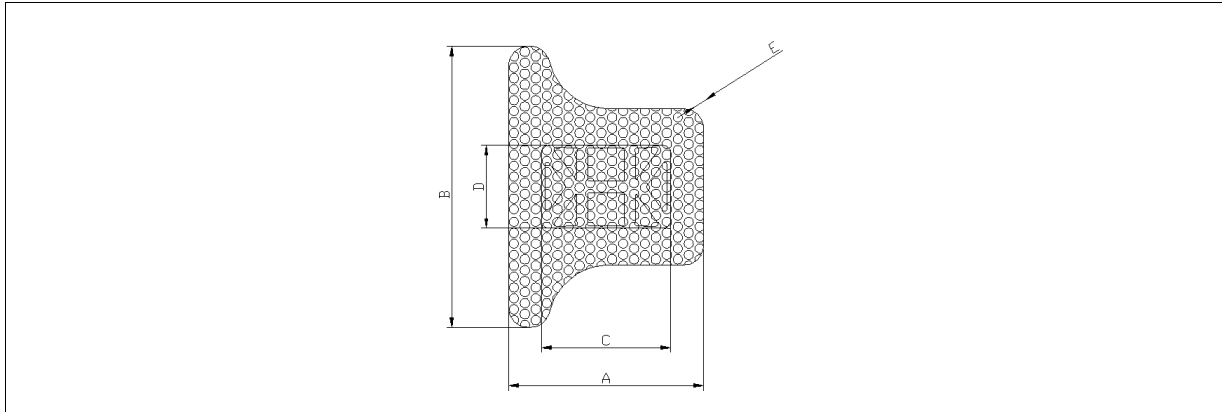
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19	PMB3338	38.0	33.0	19.8	14.85	0.25



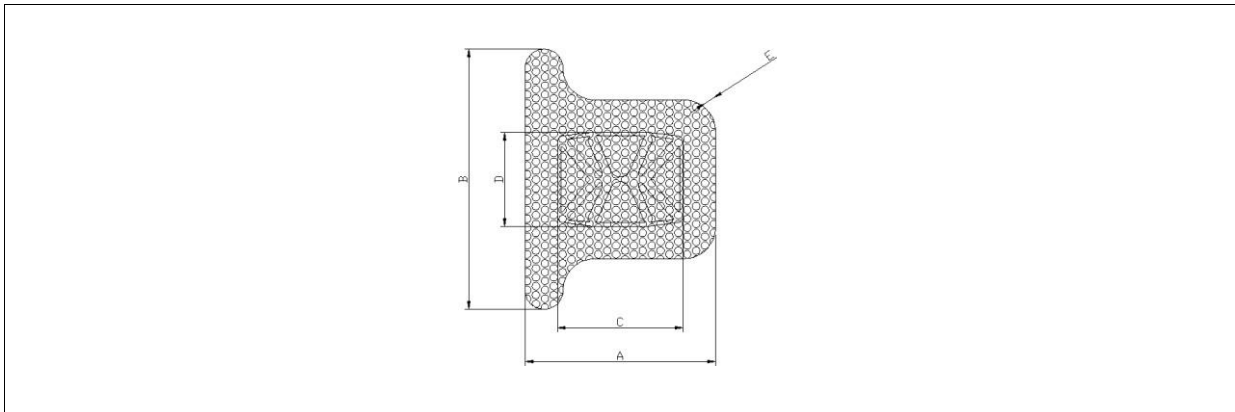
No	Model	A(mm)	B(mm)	C(mm)	D(mm)	E(Thickness)
20	PMB3040S	40.0	30.0	28.2	17.1	0.25



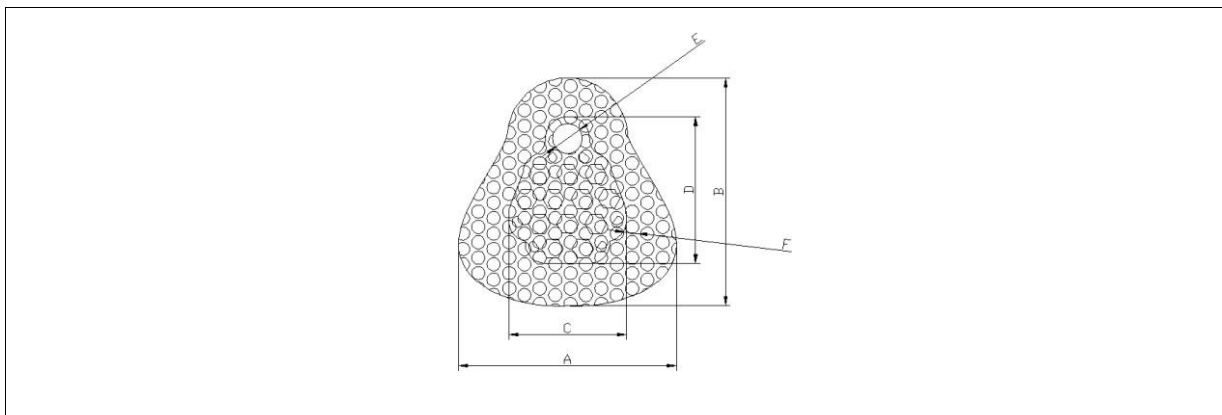
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21	PMB3040	40.0	30.0	26.8	25.03	0.25



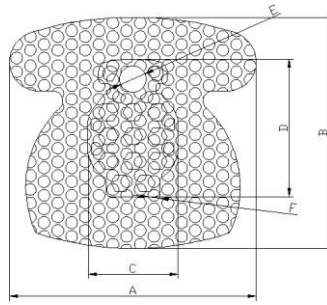
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22	PMB2536	25.0	36.0	16.59	10.6	0.25



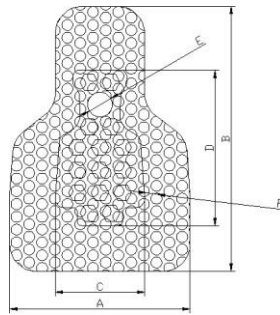
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23	PMB3041	30.0	41.0	19.8	14.85	0.25



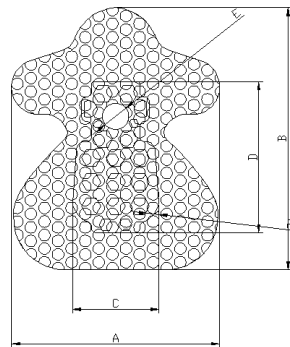
No	Model	A(mm)	B(mm)	C(mm)	D(mm)	E(Ø)	F(Thickness)
24	PMB2021	19.8	20.71	10.7	13.35	2.7	0.25



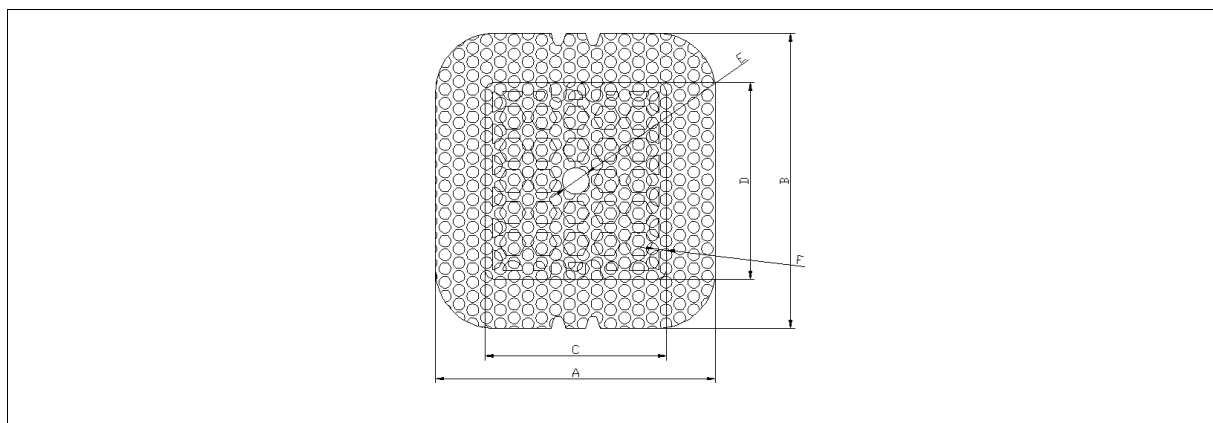
No	Model	A(mm)	B(mm)	C(mm)	D(mm)	E(Ø)	F(Thickness)
25	PMB2325	25.16	23.56	9.15	14.02	2.7	0.25



No	Model	A(mm)	B(mm)	C(mm)	D(mm)	E(Ø)	F(Thickness)
26	PMB2029	19.82	29	9.85	17	2.7	0.25



No	Model	A(mm)	B(mm)	C(mm)	D(mm)	E(Ø)	F(Thickness)
27	PMB2127	21.44	15.59	8.91	15.59	2.7	0.25



No	Model	A(mm)	B(mm)	C(mm)	D(mm)	E(Ø)	F(Thickness)
28	PMB2830	28.4	30	18.4	20	2.7	0.25
29	PMB2025	24.9	20	14.9	10	2.7	0.25
30	PMB2028	28.4	20	18.4	10	2.7	0.25
31	PMB2530	24.9	30	14.9	20	2.7	0.25

5. Indication for use

Bio-MEM Ti Reinforced membranes are an implantable temporary non-resorbable device (membrane) for use as a spacer creation barrier in the treatment of local defects in the oral cavity in conjunction with tissue regeneration or augmentation. **Bio-MEM Ti Reinforced membranes** are intended to be submerged and clinically implanted more than 30 days and no longer than 6 months.

6. Comparison with Primary Predicate Device and Reference Predicate Device

Subject	Subject Device	Primary Predicate Device	Reference Predicate Device	Comment
Product Name	Bio-MEM Ti reinforced Membrane	Neoss Ti-Reinforced Membrane	Cytoplast Regentex™ Titanium 250	
510(k)	K210797	K143327	K972278	
Manufacturer	B&Medi Co., Ltd.	Neoss, Ltd	Osteogenics biomedical Co., Ltd	
Indications for use	Bio-MEM Ti Reinforced membranes are an implantable temporary non- resorbable device (membrane) for use as a spacer creation barrier in the treatment of local defects in the oral cavity in conjunction with tissue regeneration or augmentation. Bio-MEM Ti Reinforced membranes are intended to be submerged and clinically implanted more than 30 days and no longer than 6 months.	Ti Reinforced Membrane is an implantable temporary non-resorbable device (membrane) for use as a spacer creation barrier in the treatment of local defects in the oral cavity in conjunction with tissue regeneration or augmentation. Neoss membranes are intended to be submerged and clinically implanted more than 30 days with an expected duration of implantation up of 6 months.	A Temporarily implantable material (non-resorbable) for use as a space-making barrier in the treatment of periodontal defects.	Wording is similar and principle of operation is the same

Code	NPK	NPK	LYC	
Design	A variety of configurations. May be trimmed and shaped to fit bone defect. For further information, please see 4. Description	5 configurations. May be trimmed and shaped to fit bone defect.	8 configurations. May be trimmed and shaped to fit bone defect	Geometries are similar to the predicate and reference devices. Thickness and density are within the range of predicate and reference devices. Usage and sterilization are the same.
Material	PTFE (Polytetrafluoroethylene) membranes reinforced with a Titanium frame	ePTFE and dense PTFE membranes reinforced with a Titanium frame	High density PTFE membranes reinforced with a Titanium frame	
Thickness	0.25mm	0.3mm	0.23mm	
Density	3.5g/d m ²	3.5g/d m ²	4.0g/d m ²	
Usage	Single use only	Single use only	Single use only	
Biocompatibility	Yes	Yes	Yes	
Sterilization	EO Gas Sterilization	EO Gas Sterilization	EO Gas Sterilization	

7. Technological Characteristics

As summarized in the comparison Table above, the geometries of Bio-MEM Ti Reinforced membranes are similar to the primary predicate device, Neoss Ti-Reinforced Membrane and the reference device, Cytoplast Regentex™ Titanium 250 as featured in the labeling for the predicate and reference devices. The thickness and density are in the range of the predicate and reference devices. Both the subject and predicate devices are comprised of biocompatible nonresorbable PTFE and Titanium and biocompatibility tests (see 8. Performance Testing) support substantially equivalent biocompatibility. The PTFE material of Bio-MEM device is similar in density (mass/area) and thickness to both the predicate and reference devices. The dense material of the Bio-MEM membrane is similar to the Cytoplast membrane. The intended use, principle of operation, and sterilization are the same between the subject and predicate devices.

8. Performance Testing

The Bio-MEM Ti Reinforced Membrane was evaluated for Bend and Delamination Testing in order to confirm the strength, integrity and functionality of the device. Sterilization validation and packaging validation were conducted to support EO sterilization and packaging shelf-life of 5 years. Cytotoxicity, sensitization, irritation, acute systemic toxicity, material-mediated pyrogenicity, genotoxicity (AMES and micronucleus), and implantation testing support biocompatibility of the subject device.

The subject device and processes were tested according to the following standards:

- ◆ ISO 10993-3 (2014) Biological evaluation of medical devices Part3, Test for Genotoxicity, Carcinogenicity and Reproductive Toxicity.
- ◆ ISO 10993-5 Biological Evaluation Of Medical Devices: Test for in vitro

cytotoxicity

- ◆ ISO 10993-6(2007) Biological evaluation of medical devices – Part 6: Tests for local effects after implantation.
- ◆ ISO 10993-7[2008] Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
- ◆ ISO 10993-10 Biological evaluation of medical devices - part 10: tests for irritation and skin sensitization
- ◆ ISO 10993-10 Biological evaluation of medical devices - part 11: tests for systemic toxicity, 5 Acute systemic toxicity
- ◆ ISO 11135 [2014] Validation and routine control of ethylene oxide sterilization
- ◆ ASTM D4895 - 10 Standard Specification for Polytetrafluoroethylene (PTFE) Resin Produced From Dispersion
- ◆ ISO11607, ISO11737, ASTM F1980, ASTM F88, ASTM F1929:2012. Standards which the tests were used in the packaging validation.
- ◆ USP 29 Biological tests <151> Pyrogen Test

9. Clinical Testing

Clinical Data was not required to establish the substantial equivalence of the Bio-MEM Ti Reinforced Membrane.

10. Conclusion

The Bio-MEM Ti Reinforced Membrane is similar to legally marketed devices listed previously in that they share similar indications for use and incorporate similar technological characteristics. All evaluations determined that the Bio-MEM Ti Reinforced Membrane is substantially equivalent to the predicate devices.