Class 2 Device Recall Healon

See Related Information[22]

Date Initiated by Firm	April 01, 2017
Create Date	May 10, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-2062-2017
Recall Event ID	77023[23]
PMA Number	P810031[24]
Product Classification	Aid, surgical, viscoelastic[25] - **Product Code** LZP[26]
Product	Healon, Part No. 10290953, 10295210, 10200011, 10200012, 10201012, 10203012, 10213012, 10223012, 10290701, 10294751, 10295701
Code Information	UB32602, UB32593, UB32514, UB32521, UB32579, UB32573, UB32599, UB32614, UB32616, UB32533
Recalling Firm/ Manufacturer	Abbott Medical Optics Inc. (AMO) 1700 E Saint Andrew Pl Santa Ana CA 92705-4933
For Additional Information Contact	714-247-8200
Manufacturer Reason for Recall	Remote possibility that certain solutions in these lots may contain microscopic glass particles due to damage that occurred at the cylinder neck during the manufacturing process.
FDA Determined Cause [2]	Process design
Action	A recall letter was sent to customers on 4/1/17 to inform them that AMO has voluntarily initiated this Action because a remote possibility exists that certain Healon OVD solutions in the affected lots may contain microscopic glass particles due to damage that occurred at the cylinder neck during the manufacturing process. Use of OVD solutions with glass particles could potentially lead to intraocular injury. Customers are instructed to complete the Customer Reply Form and fax it to AMO Quality Assurance at 714-247-4510 or email to RegCompliOne@abbott.com within 3 business days of receipt of the letter. Customers with product complaints or adverse events are instructed to inform AMO by calling 877-266-4543. Customers that do report a complaint are instructed to provide the Healon OVD lot number and, if a patient was involved, the date of surgery, a description of the event and patient outcome.
Quantity in Commerce	293,867 units total
Distribution	US and worldwide: Austria Belgium Croatia Czech Republic Denmark Finland France Germany Great Britain Iceland Ireland Israel Italy Latvia Lebanon Lithuania Netherlands Norway Portugal Spain Sweden Switzerland Tunisia Turkey Russian Fed Guadeloupe Sri Lanka Australia China Hong Kong Indonesia Malaysia Singapore South Korea Taiwan Thailand Japan Chile Colombia Costa Rica Ecuador
Total Product Life Cycle	TPLC Device Report[27]

Class 2 Device Recall Healon Duet

See Related Information[22]

Date Initiated by Firm	April 01, 2017
Create Date	May 10, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-2064-2017
Recall Event ID	77023[23]
PMA Number	P810031[24]
Product Classification	Aid, surgical, viscoelastic[25] - **Product Code** LZP[26]
Product	Healon Duet, Part No. 10290080, 10220010, 10220011 and 10220012
Code Information	UB32636
Recalling Firm/ Manufacturer	Abbott Medical Optics Inc. (AMO) 1700 E Saint Andrew Pl Santa Ana CA 92705-4933
For Additional Information Contact	714-247-8200
Manufacturer Reason for Recall	Remote possibility that certain solutions in these lots may contain microscopic glass particles due to damage that occurred at the cylinder neck during the manufacturing process.
FDA Determined Cause [2]	Process design
Action	A recall letter was sent to customers on 4/1/17 to inform them that AMO has voluntarily initiated this Action because a remote possibility exists that certain Healon OVD solutions in the affected lots may contain microscopic glass particles due to damage that occurred at the cylinder neck during the manufacturing process. Use of OVD solutions with glass particles could potentially lead to intraocular injury. Customers are instructed to complete the Customer Reply Form and fax it to AMO Quality Assurance at 714-247-4510 or email to RegCompliOne@abbott.com within 3 business days of receipt of the letter. Customers with product complaints or adverse events are instructed to inform AMO by calling 877-266-4543. Customers that do report a complaint are instructed to provide the Healon OVD lot number and, if a patient was involved, the date of surgery, a description of the event and patient outcome.
Quantity in Commerce	293,867 units total
Distribution	US and worldwide: Austria Belgium Croatia Czech Republic Denmark Finland France Germany Great Britain Iceland Ireland Israel Italy Latvia Lebanon Lithuania Netherlands Norway Portugal Spain Sweden Switzerland Tunisia Turkey Russian Fed Guadeloupe Sri Lanka Australia China Hong Kong Indonesia Malaysia Singapore South Korea Taiwan Thailand Japan Chile Colombia Costa Rica Ecuador
Total Product Life Cycle	TPLC Device Report[27]

Class 2 Device Recall Healon 5 Pro

See Related Information[22]

Date Initiated by Firm	April 01, 2017
Create Date	May 10, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-2065-2017
Recall Event ID	77023[23]
PMA Number	P810031[24]
Product Classification	Aid, surgical, viscoelastic[25] - **Product Code** LZP[26]
Product	Healon 5 Pro, Part No. 10270015
Code Information	UB32526
Recalling Firm/ Manufacturer	Abbott Medical Optics Inc. (AMO) 1700 E Saint Andrew Pl Santa Ana CA 92705-4933
For Additional Information Contact	714-247-8200
Manufacturer Reason for Recall	Remote possibility that certain solutions in these lots may contain microscopic glass particles due to damage that occurred at the cylinder neck during the manufacturing process.
FDA Determined Cause [2]	Process design
Action	A recall letter was sent to customers on 4/1/17 to inform them that AMO has voluntarily initiated this Action because a remote possibility exists that certain Healon OVD solutions in the affected lots may contain microscopic glass particles due to damage that occurred at the cylinder neck during the manufacturing process. Use of OVD solutions with glass particles could potentially lead to intraocular injury. Customers are instructed to complete the Customer Reply Form and fax it to AMO Quality Assurance at 714-247-4510 or email to RegCompliOne@abbott.com within 3 business days of receipt of the letter. Customers with product complaints or adverse events are instructed to inform AMO by calling 877-266-4543. Customers that do report a complaint are instructed to provide the Healon OVD lot number and, if a patient was involved, the date of surgery, a description of the event and patient outcome.
Quantity in Commerce	293,867 units total
Distribution	US and worldwide: Austria Belgium Croatia Czech Republic Denmark Finland France Germany Great Britain Iceland Ireland Israel Italy Latvia Lebanon Lithuania Netherlands Norway Portugal Spain Sweden Switzerland Tunisia Turkey Russian Fed Guadeloupe Sri Lanka Australia China Hong Kong Indonesia Malaysia Singapore South Korea Taiwan Thailand Japan Chile Colombia Costa Rica Ecuador
Total Product Life Cycle	TPLC Device Report[27]

Class 2 Device Recall Healon GV

See Related Information[22]

Date Initiated by Firm	April 01, 2017
Create Date	May 10, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-2063-2017
Recall Event ID	77023[23]
PMA Number	P810031[24]
Product Classification	Aid, surgical, viscoelastic[25] - **Product Code** LZP[26]
Product	Healon GV, Part No. 10294701, 10294801, 10200014, 10201014, 10202014, 10203014
Code Information	UB32596, UB32571, UB32597, UB32577, UB32576
Recalling Firm/ Manufacturer	Abbott Medical Optics Inc. (AMO) 1700 E Saint Andrew Pl Santa Ana CA 92705-4933
For Additional Information Contact	714-247-8200
Manufacturer Reason for Recall	Remote possibility that certain solutions in these lots may contain microscopic glass particles due to damage that occurred at the cylinder neck during the manufacturing process.
FDA Determined Cause [2]	Process design
Action	A recall letter was sent to customers on 4/1/17 to inform them that AMO has voluntarily initiated this Action because a remote possibility exists that certain Healon OVD solutions in the affected lots may contain microscopic glass particles due to damage that occurred at the cylinder neck during the manufacturing process. Use of OVD solutions with glass particles could potentially lead to intraocular injury. Customers are instructed to complete the Customer Reply Form and fax it to AMO Quality Assurance at 714-247-4510 or email to RegCompliOne@abbott.com within 3 business days of receipt of the letter. Customers with product complaints or adverse events are instructed to inform AMO by calling 877-266-4543. Customers that do report a complaint are instructed to provide the Healon OVD lot number and, if a patient was involved, the date of surgery, a description of the event and patient outcome.
Quantity in Commerce	293,867 units total
Distribution	US and worldwide: Austria Belgium Croatia Czech Republic Denmark Finland France Germany Great Britain Iceland Ireland Israel Italy Latvia Lebanon Lithuania Netherlands Norway Portugal Spain Sweden Switzerland Tunisia Turkey Russian Fed Guadeloupe Sri Lanka Australia China Hong Kong Indonesia Malaysia Singapore South Korea Taiwan Thailand Japan Chile Colombia Costa Rica Ecuador
Total Product Life Cycle	TPLC Device Report[27]

Class 2 Device Recall Healon V

See Related Information[22]

Date Initiated by Firm	April 01, 2017
Create Date	May 10, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-2067-2017
Recall Event ID	77023[23]
PMA Number	P810031[24]
Product Classification	Aid, surgical, viscoelastic[25] - **Product Code** LZP[26]
Product	Healon V, Part No. 10290045
Code Information	UB32491
Recalling Firm/ Manufacturer	Abbott Medical Optics Inc. (AMO) 1700 E Saint Andrew Pl Santa Ana CA 92705-4933
For Additional Information Contact	714-247-8200
Manufacturer Reason for Recall	Remote possibility that certain solutions in these lots may contain microscopic glass particles due to damage that occurred at the cylinder neck during the manufacturing process.
FDA Determined Cause [2]	Process design
Action	A recall letter was sent to customers on 4/1/17 to inform them that AMO has voluntarily initiated this Action because a remote possibility exists that certain Healon OVD solutions in the affected lots may contain microscopic glass particles due to damage that occurred at the cylinder neck during the manufacturing process. Use of OVD solutions with glass particles could potentially lead to intraocular injury. Customers are instructed to complete the Customer Reply Form and fax it to AMO Quality Assurance at 714-247-4510 or email to RegCompliOne@abbott.com within 3 business days of receipt of the letter. Customers with product complaints or adverse events are instructed to inform AMO by calling 877-266-4543. Customers that do report a complaint are instructed to provide the Healon OVD lot number and, if a patient was involved, the date of surgery, a description of the event and patient outcome.
Quantity in Commerce	293,867 units total
Distribution	US and worldwide: Austria Belgium Croatia Czech Republic Denmark Finland France Germany Great Britain Iceland Ireland Israel Italy Latvia Lebanon Lithuania Netherlands Norway Portugal Spain Sweden Switzerland Tunisia Turkey Russian Fed Guadeloupe Sri Lanka Australia China Hong Kong Indonesia Malaysia Singapore South Korea Taiwan Thailand Japan Chile Colombia Costa Rica Ecuador
Total Product Life Cycle	TPLC Device Report[27]

Class 2 Device Recall Healon Pro

See Related Information [22]

Date Initiated by Firm	April 01, 2017
Create Date	May 10, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-2066-2017
Recall Event ID	77023[23]
PMA Number	P810031[24]
Product Classification	Aid, surgical, viscoelastic[25] - **Product Code** LZP[26]
Product	Healon Pro, Part No. 10270012
Code Information	UB32524
Recalling Firm/ Manufacturer	Abbott Medical Optics Inc. (AMO) 1700 E Saint Andrew Pl Santa Ana CA 92705-4933
For Additional Information Contact	714-247-8200
Manufacturer Reason for Recall	Remote possibility that certain solutions in these lots may contain microscopic glass particles due to damage that occurred at the cylinder neck during the manufacturing process.
FDA Determined Cause [2]	Process design
Action	A recall letter was sent to customers on 4/1/17 to inform them that AMO has voluntarily initiated this Action because a remote possibility exists that certain Healon OVD solutions in the affected lots may contain microscopic glass particles due to damage that occurred at the cylinder neck during the manufacturing process. Use of OVD solutions with glass particles could potentially lead to intraocular injury. Customers are instructed to complete the Customer Reply Form and fax it to AMO Quality Assurance at 714-247-4510 or email to RegCompliOne@abbott.com within 3 business days of receipt of the letter. Customers with product complaints or adverse events are instructed to inform AMO by calling 877-266-4543. Customers that do report a complaint are instructed to provide the Healon OVD lot number and, if a patient was involved, the date of surgery, a description of the event and patient outcome.
Quantity in Commerce	293,867 units total
Distribution	US and worldwide: Austria Belgium Croatia Czech Republic Denmark Finland France Germany Great Britain Iceland Ireland Israel Italy Latvia Lebanon Lithuania Netherlands Norway Portugal Spain Sweden Switzerland Tunisia Turkey Russian Fed Guadeloupe Sri Lanka Australia China Hong Kong Indonesia Malaysia Singapore South Korea Taiwan Thailand Japan Chile Colombia Costa Rica Ecuador
Total Product Life Cycle	TPLC Device Report[27]